IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, *ex rel.* DAVID M. KESTER, et al., Plaintiffs, v. NOVARTIS PHARMACEUTICAL CORPORATION, et al., Defendants.	Civil Action No. 1:11-cv-08196 (CM) **ECF CASE**

PLAINTIFFS' PROPOSED JURY INSTRUCTIONS

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I. OVERVIEW OF PLAINTIFFS' PROPOSED JURY INSTRUCTIONS

Plaintiffs respectfully submit these proposed instructions in accordance with Rule V.C. of the Court's Individual Rules of Practice. In preparing these instructions, we tried to tailor them based on the nature of this case, issues to be tried, and the Court's prior decisions. Thus, we have specified the instances where, based on the Court's prior decisions or the parties' positions, an element of a claim or defense has been decided as a matter of law or is not in dispute.

Most significantly, the Court previously held that, once Plaintiffs establish that compliance with the Anti-Kickback Statute (the "AKS") was a condition of payment under Medicare or Medicaid or that the pharmacies expressly certified their compliance with all applicable law, and that the AKS was violated, then the claims for payment in this case are "legally false." *United States ex rel. Kester v. Novartis Pharm. Corp.*, 41 F. Supp. 3d 323, 329 (S.D.N.Y. 2014) ("*Novartis IV*"). The Court ruled that the AKS, as amended on March 23, 2010, established such a legal "condition of payment" for Medicare and Medicaid after that point in time. *Id.* at 330-31; *see also U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 43 F. Supp. 3d 332, 364 (S.D.N.Y. 2014) ("*Novartis V*"). Similarly, the Court ruled that state laws "expressly stat[ing] that a pharmacy must comply with [applicable laws including] the AKS in order to be paid for claims submitted to … Medicaid" establish AKS compliance as a condition of payment.[1] *United States ex rel. Kester v. Novartis Pharm. Corp.*, 2014 WL 4401275, at *9-10 (S.D.N.Y. Sept. 4, 2014) ("*Novartis VI*"). Finally, the Court ruled that the AKS is an "applicable" law with regard to Medicare and Medicaid, *Novartis IV*, 41 F. Supp. 3d at 331, and

[1] The Court's "implied certification" holding applies to the non-intervening States that have similar statutes or regulations expressly conditioning Medicaid reimbursement on compliance with laws like the AKS. To the extent that Novartis disputes which non-intervening States have laws or regulations giving rise to "implied certification" liability, we expect that this issue will be addressed by motion practice in advance of the trial.

that any pharmacy's express certification of compliance with "applicable" law would necessarily certify compliance with the AKS. *See Novartis IV*, 41 F. Supp. 3d at 338 (NY certification of compliance with applicable law); *United States ex rel. Kester v. Novartis Pharm. Corp.*, 2015 WL 109934, at *18-20 (S.D.N.Y. Jan. 6, 2015) ("*Novartis VIII*") (remaining states); *id.* at *17 (Medicare Part D contracts).

Thus, the basic issues for the jury to decide are, *first*, whether defendant Novartis engaged in kickback relationships with each of the Exjade and/or Myfortic pharmacies in violation of the AKS; *second*, whether Novartis knowingly caused the pharmacy in question to submit false Medicare and Medicaid claims and/or conspired with the pharmacy to do so; and, *third*, the duration of each of the kickback relationships. Accordingly, we submit that, if the jury answers the first two questions in the affirmative, then the damages and penalties associated with the false claims submitted during the relevant periods should be resolved by the Court. *See United States ex rel. Feldman v. Van Gorp*, 697 F.3d 78, 92 (2d Cir. 2012) ("[I]nasmuch as the damages equal the full amount that the government paid and that amount is not in dispute, they were properly determined by the district court as a matter of law."); *Chandler v. Cook County*, 538 U.S. 119, 133 (2003) ("[T]he court alone sets any separate penalty.").

In addition, although Novartis waived privilege with respect to Exjade to assert it relied on the advice-of-counsel, discovery has shown that the elements of that defense are not met: *first*, Novartis failed to provide all relevant facts to its attorneys; *second*, Novartis's attorneys did not advise that the proposed transactions were legal; and, *third*, Novartis did not rely in good faith on the advice provided by its attorneys. Thus, we submit that Novartis cannot make the threshold showing to present an advice of counsel defense. *See Markowski v. SEC*, 34 F.3d 99, 104-05 (2nd Cir. 1994) (defendant may not rely upon advice of counsel defense if defendant

either: (i) failed to make complete disclosure to counsel; (ii) did not receive advice that its conduct was legal; or (iii) did not rely on that advice in good faith); *United States v. King*, 560 F.2d 122, 132 (2d Cir. 1977) (declining to charge the jury on the advice-of-counsel defense when defendant made no showing that he provided all relevant facts to his attorney).

Finally, in the event that the Court decides to charge the jury on issues of the number of false claims, amount of penalties, damages, or good faith reliance on advice of counsel defense, we have included Plaintiffs' proposed instructions on those issues in an addendum to these proposed instructions. Likewise, Plaintiffs respectfully reserve their right to amend and/or supplement these proposed jury instructions and the special verdict form in light of any decision from the Court or in response to arguments or defenses raised by Novartis.[2]

[2] In this regard, Plaintiffs understand that Novartis likely will assert an affirmative defense based on the discount safe harbor under the Anti-Kickback Statute. We therefore include below a proposed instruction regarding that contention. Plaintiffs also may submit a supplement to the proposed special verdict form to the extent that the Court may ask the jury to decide any question relating to the discount safe harbor.

II. PRELIMINARY INSTRUCTIONS

(To Be Read Before Opening Statements)

INSTRUCTION NO. 1: Opening Instructions

We are about to begin the trial of the case you heard about during the jury selection. Before the trial begins, I am going to give you instructions that will help you to understand what will be presented to you and how you should conduct yourself during the trial.

During the trial you will hear me use a few terms that you may not have heard before. Let me briefly explain some of the most common to you. The parties who are suing are called the plaintiffs. In this case, the plaintiffs are the United States Government, the States of California, Georgia, Illinois, Indiana, Maryland, Michigan, New Jersey, New York, Oklahoma, Wisconsin, and Washington; and the Relator, David Kester. I will explain to you the relator's role in a moment.

The party being sued is called the defendant. In this case, the defendant is a corporation called Novartis Pharmaceuticals Corporation, otherwise known as "Novartis."

You will sometimes hear me refer to "counsel." "Counsel" is another way of saying "lawyer" or "attorney."

I will sometimes refer to myself as the "Court."

When I "sustain" an objection, I am excluding the challenged evidence from this trial for a good reason. When you hear that I have "overruled" an objection, I am permitting that evidence to be admitted.

When I say "admitted into evidence" or "received into evidence," I mean that the particular statement or the particular exhibit may be considered by you in making the decisions you must make at the end of the case.

By your verdict, you will decide disputed issues of fact. I will decide all questions of law that arise during the trial. Before you begin your deliberation at the close of the case, I will instruct you in more detail on the law that you must follow and apply.

Because you will be asked to decide the facts of this case, you should give careful attention to the testimony and evidence presented. Keep in mind that I will instruct you at the end of the trial about determining the credibility or "believability" of the witnesses. During the trial you should keep an open mind and should not form or express any opinion about the case until you have heard all of the testimony and evidence, the lawyers' closing arguments, and my instructions to you on the law.

While the trial is in progress, you must not discuss the case in any manner amongst yourselves or with anyone else. In addition, you should not permit anyone to discuss the case in your presence.

From time to time during the trial, I may make rulings on objections or motions made by the lawyers. It is a lawyer's duty to object when the other side offers testimony or other evidence that the lawyer believes is not admissible. You should not be unfair or partial against a lawyer or the lawyer's client because the lawyer has made objections. You should not infer or conclude from any ruling or other comment I may make that I have any opinions on the merits of the case favoring one side or the other. I do not favor one side or the other.

The trial lawyers are not allowed to speak with you during this case. When you see them at a recess or pass them in the halls and they do not speak to you, they are not being rude or unfriendly; they are simply following the law. During the trial, it may be necessary for me to talk with the lawyers out of your hearing about questions of law or procedure. Sometimes, you may be excused from the courtroom during these discussions. I will try to limit these interruptions as

much as possible, but you should remember the importance of the matter you are here to determine and should be patient even though the case may sometimes seem to go slowly.

Source: O'Malley, Grenig and Lee, *Federal Jury Practice and Instructions* (5th Ed.) ("*FJPI*") § 101.01.

INSTRUCTION NO. 2: Nature of Case

This trial is in a civil case. The Plaintiffs are the United States Government, eleven States, and the Relator, a private individual who is asserting claims on behalf of the United States Government and a number of states. These Plaintiffs are suing Novartis because they claim that Novartis engaged in fraud on Medicare and Medicaid, two government-funded healthcare programs, in violation of a federal law called the False Claims Act and similar State laws. Novartis is a corporation that manufactures and markets a variety of drugs, including, as relevant to this trial, an iron chelation drug called Exjade and an immunosuppressant drug called Myfortic.

Let me explain to you one feature of the False Claims Act. The False Claims Act contains whistleblower provisions that allow a private whistleblower, who is called the Relator, to initiate a lawsuit on behalf of the United States Government and States that enacted their own False Claims Acts.[3] The United States Government and the States can investigate and then decide whether to join the lawsuit.

Here, the private whistleblower who initiated this case is David Kester, a former Novartis sales manager. Mr. Kester initiated this case in November 2011 by filing a complaint under seal. Between 2011 and 2013, the case remained under seal while the Government investigated Mr. Kester's allegations to decide whether to join his lawsuit. In 2013, the United States and eleven States decided to join this lawsuit and will prosecute their claims at this trial, and attorneys for the Relator, David Kester, will be pursuing claims on behalf of the District of Columbia and 16 States that have not joined the lawsuit.

When I use the term "Plaintiffs," I am referring to both the federal and state government entities who will be presenting their claims at trial as well as the Relator David Kester.

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[3] 31 U.S.C. § 3730; *see generally U.S. ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13, 15 (1st Cir. 2009) ("the qui tam provisions of the False Claims Act … allow whistleblowers (called 'relators') to bring certain fraud claims on behalf of the United States").

Why are Plaintiffs claiming that Novartis violated the False Claims Act? Plaintiffs allege that Novartis orchestrated kickback schemes involving Exjade and Myfortic. With respect to Exjade, Plaintiffs allege that Novartis, with a purpose of inducing three specialty pharmacies, Accredo, BioScrip, and US Bioservices, to recommend to patients that they order Exjade refills, offered and gave patient referrals and so-called rebates to those three pharmacies. With respect to Myfortic, Plaintiffs allege that Novartis offered and paid five specialty pharmacies kickbacks in the form of so-called "performance benefits" with a purpose of inducing those pharmacies to recommend Myfortic over a competitor drug called CellCept and over generic versions of CellCept.

Plaintiffs allege that, by engaging in these kickback schemes, Novartis violated a federal law called the Anti-Kickback Statute and similar state laws that prohibit offering, giving, soliciting, or accepting things of value in exchange for recommending drugs or other products that are reimbursed by Medicare or Medicaid. Plaintiffs assert that Novartis also violated a federal law called the False Claims Act. Plaintiffs allege that Novartis, by engaging in the kickback schemes, violated the False Claims Act in three separate ways — first, Novartis caused false or fraudulent claims to be submitted to Medicare and Medicaid by the pharmacies; second, Novartis made or used false statements, or caused the pharmacies to make or use false statements, material to false claims submitted to Medicare and Medicaid; and, third, Novartis and the pharmacies conspired to violate the False Claims Act.

Before you retire for your deliberations, I will give you brief backgrounds on both the False Claims Act and Anti-Kickback Statute, as well as the specific elements of each that the Plaintiffs will need to prove by a preponderance of the evidence in order to recover.[4]

[4] 31 U.S.C. § 3731(d) ("In any action brought under [the False Claims Act], the United States shall be required to prove all essential elements of the cause of action, including damages, by a preponderance of the evidence"). Given the clear language of the FCA, "any action" necessarily includes an action predicated on an AKS violation. Courts have consistently held that

What does "preponderance of the evidence mean?" It simply means that, as to each element of the relevant laws, the Plaintiffs must show that it was more likely than not that the thing was done. You may have heard the phrase "beyond a reasonable doubt." That only applies to criminal trials, and you should put that phrase out of your minds.

You will also hear a lot about federal healthcare programs. "Federal healthcare programs" means any plan or program that provides health benefits, which is funded directly or indirectly by the United States government. For purposes of this trial, federal healthcare programs include both Medicare and Medicaid.

Sources: 31 U.S.C. § 3729; Corrected Joint Pre-Trial Order; *FJPI* § 104:41.

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preponderance of the evidence is the correct standard to apply to all of the elements in a FCA case based on AKS violations, including the AKS elements. *See United States v. Rogan*, 459 F. Supp. 2d 692, 716 n.12 (N.D. Ill. 2006), *aff'd.* 517 F.3d 449 (7th Cir. 2008) (holding that, in an FCA action, underlying AKS violations need only be proved by a preponderance); *see also U.S. ex rel. Health Dimensions Rehab., Inc. v. Rehabcare Group, Inc.* 2013 U.S. Dist. LEXIS 135498 (E.D. Mo. Sept. 23, 2013) (granting government's motion *in limine* to exclude argument as to any burden of proof other than a preponderance of evidence in FCA case predicated on AKS violations); *Fed. Crop Ins. Corp. v. Hester*, 765 F.2d 723, 727-28 (8th Cir. 1980) (applying preponderance standard prior to the amendment of the AKS to specify such a burden of proof).

III. PROCEDURAL INSTRUCTIONS

(To Be Read After the Close of Evidence)

INSTRUCTION NO. 3: Jurors' Duty to Deliberate

Now that you have heard all of the evidence to be received in this trial and each of the arguments of counsel, it becomes my duty to give you the final instructions of the Court as to the law that is applicable to this case and which will guide you in your decisions. All of the instructions of law given to you by the Court – those given to you at the beginning of the trial, those given to you during the trial, and these final instructions – must guide and govern your deliberations.

It is your duty as jurors to follow the law as stated in all of the instructions of the Court and to apply these rules of law to the facts as you find them from the evidence received during the trial.

Counsel have referred to some of the applicable rules of law in their closing arguments to you. However, if what counsel says about the law differs from what I say about the law, you are to follow the instructions given to you by the Court.

You are not to focus on any single instruction, but must consider my charge as a whole in reaching your decisions.

You must not be concerned with the wisdom of any rule of law stated by the Court. It would violate your sworn duty to base your verdict on some view or opinion about what the law ought to be, rather than on the law as I give it to you—just as it would violate your sworn duty, as judges of the facts, to base your verdict on anything but the evidence received in the case.

Source: *FJPI* § 103:1.

INSTRUCTION NO. 4: Burden of Proof

This is a civil case and as such the Plaintiffs have the burden of proving the material allegations of their claims.

If after considering all of the testimony you are satisfied that the Plaintiffs have carried their burden on each essential point as to which they have the burden of proof, then you must find for the Plaintiffs on their claims. If after such consideration you find the testimony of both parties to be in balance or equally probable, then the Plaintiffs have failed to sustain their burden and you must find for the defendant.

If upon a consideration of all the facts on the issue of one of Plaintiffs' claims you find that Plaintiffs have failed to sustain the burden cast upon them, then you should proceed no further and return a verdict for the defendant. If, however, you find that Plaintiffs have sustained the burden on this issue, then you should proceed to consider the issue of the defendant's affirmative defenses. At this stage, the burden is upon the defendant to establish the affirmative defense by a preponderance of the evidence. If you determine that the defendant has sustained its burden of establishing the affirmative defense by a preponderance of the evidence, then you should proceed no further and return a verdict for the defendant. If, however, you find that the defendant has not sustained its burden as to the affirmative defense, then you should return a verdict for the plaintiffs on the issue.

Source: Sand, 4-73 Modern Federal Jury Instructions-Civil P 73.01 (Lexis 2015).

INSTRUCTION NO. 5: Decision on the Evidence

You will find the facts from one thing only — the evidence.

The evidence in this case consists of the sworn testimony of the witnesses; all exhibits received in evidence, regardless of who may have produced them; and all facts that may have been agreed to or stipulated, which you are to regard as proved.

Nothing I say is evidence. Nothing any of the lawyers say is evidence. Questions by themselves are not evidence. Objections are not evidence. You must disregard any evidence to which an objection was sustained by the Court, and any evidence I ordered stricken.

I am neutral in this matter. I do not decide the factual issues of this case. That is not my job; it is yours, and I leave it entirely to you. My function was to get the trial concluded as fairly and promptly as possible, and to explain the law to you; the decision in the case is yours.

So, do not get any notion that I have a certain attitude or view about the case. I do not. Do not draw any inferences about my views from rulings I have made during the trial. For example, from time to time the lawyers have, quite properly, objected when they thought a question violated the rules of evidence. (That is their job; so don't hold it against them.) I make a call just like an umpire at a baseball game makes a call. My "call" does not indicate that I favor one verdict or the other. I am not sending you signals with my rulings.

In making your findings based on the evidence received, you are permitted to draw reasonable inferences from the facts that you find have been proved from the testimony and the exhibits. Inferences are simply deductions or conclusions that reason and common sense lead you to draw from the evidence received in the case.

Source: *United States v. Anthony Boykin, et al.*, No. 10-Cr.-391 (CM) (S.D.N.Y. Mar. 6, 2013).

INSTRUCTION NO. 6: Judging the Evidence

You should consider the evidence in a trial in the same way that any reasonable and careful person would treat any very important question involving facts, opinions, and evidence. You are expected to use your good sense in considering and evaluating the evidence in the case for only those purposes for which it has been received, and to give such evidence a reasonable and fair construction in the light of your common knowledge of the natural tendencies and inclinations of human beings.

Source: *United States v. Anthony Boykin, et al.*, No. 10-Cr.-391 (CM) (S.D.N.Y. Mar. 6, 2013).

INSTRUCTION NO. 7: Direct and Circumstantial Evidence

There are two types of evidence that you may properly consider in reaching your verdict.

One type of evidence is called direct evidence. Direct evidence is evidence given by a witness who testifies to what she saw, heard, or observed, of her own knowledge acquired by virtue of her own senses.

Circumstantial evidence is evidence that tends to prove a disputed fact by proof of other facts. There is a simple example of circumstantial evidence that is often used in the courts.

Assume that when you came into the courthouse this morning the sun was shining and it was a nice day. Assume that the courtroom blinds were drawn and you could not look outside.

As you sat here, someone walked in with an umbrella that was dripping wet. Somebody else then walked in with a raincoat that was also dripping wet.

Now, you could not look outside of the courtroom to see whether or not it was raining, so you would have no direct evidence of that fact. But, on the combination of facts that I asked you to assume, it would be reasonable and logical for you to conclude that it had been raining.

That is all there is to circumstantial evidence. You infer from an established fact the existence or the nonexistence of some other fact on the basis of your reason, experience and common sense.

Circumstantial evidence is of no less value than direct evidence. In fact, it is a general rule that the law makes no distinction between direct and circumstantial evidence. Both are properly considered by you in reaching your verdict.

Source: *United States v. Anthony Boykin, et al.*, No. 10-Cr.-391 (CM) (S.D.N.Y. Mar. 6, 2013).

INSTRUCTION NO. 8: Jury to Determine Credibility of Witnesses

You, as jurors, are the sole judges of the credibility of the witnesses and the weight their testimony deserves. You may be guided by the appearance and conduct of the witness, or by the manner in which the witness testifies, or by the character of the testimony given, or by evidence you find credible that is contrary to the testimony given.

Carefully scrutinize all the testimony you have heard, the circumstances under which each witness testified, and every matter in evidence that tends to show whether a witness is worthy of belief. Consider each witness' intelligence, motive, state of mind, and demeanor or manner while on the stand. Consider the witness' ability to observe the matters as to which he has testified, and whether he impresses you as having an accurate recollection of these matters. Consider any relation each witness may bear to either side of the case; the manner in which each witness might be affected by the verdict; and the extent to which, if at all, each witness' testimony is supported or contradicted by other evidence in the case. Consider whether the witness has lied or told the truth in the past, and whether the witness has committed acts that cast doubt on his or her credibility.

Inconsistencies or discrepancies within the testimony of a witness may cause you to discredit what the witness says to you; and inconsistencies between the testimony of different witnesses may cause you to conclude that one of the two is not telling the truth. But inconsistencies do not necessarily indicate that a witness is lying. Two or more persons who witness an incident or transaction may see or hear it differently; and innocent misrecollection, like failure of recollection, is not an uncommon experience. In weighing the effect of a discrepancy, consider whether it pertains to a matter of importance or an unimportant detail, and whether you believe it results from innocent error or intentional falsehood.

After making your own judgment, relying on whatever factors you find it appropriate to consider, you should give the testimony of each witness such weight, if any, as you may think it deserves.

Source: *United States v. Anthony Boykin, et al.*, No. 10-Cr.-391 (CM) (S.D.N.Y. Mar. 6, 2013).

INSTRUCTION NO. 9: Demonstrative Summaries

Certain charts and summaries have been shown to you in order to help explain the facts disclosed by the books, records, or other underlying evidence in the case. Those charts or summaries are used for convenience. They are not themselves evidence or proof of any facts. If they do not correctly reflect the facts shown by the evidence in the case, you should disregard these charts and summaries and determine the facts from the books, records or other underlying evidence.

Source: 8TH CIR. CIVIL JURY INSTR. § 2.11 (2013).

INSTRUCTION NO. 10: Stipulated Facts

The plaintiffs and the defendants have stipulated – that is, they have agreed – that certain facts are as counsel have just stated. You should, therefore, treat those facts as having been proved.

Source: *FJPI* § 102:11.

INSTRUCTION NO. 11: Deposition Testimony

Testimony was presented to you in the form of depositions. A deposition is the recorded answers a witness made under oath to questions asked by lawyers before trial. The deposition testimony offered was electronically videotaped and that recording played for you. You should consider the deposition testimony, and judge its credibility, as you would that of any witness who testifies here in person.

Source: 8TH CIR. CIVIL JURY INSTR. § 2.14 (2013).

INSTRUCTION NO. 12: Rule 1006 Summaries

You will remember that certain summaries and/or charts were admitted in evidence. You may use those summaries and/or charts as evidence, even though the underlying documents and records are not here.[5]

Source: 8TH CIR. CIVIL JURY INSTR. § 2.12 (2013).

[5] In the event that the parties dispute the accuracy or authenticity of any summary or chart, Plaintiffs propose the following supplement to this instruction:

> However, the [accuracy/authenticity] of this [summary/chart] has been challenged. It is for you to decide how much weight, if any, you will give to them. In making that decision, you should consider all of the testimony you heard about the way in which they were prepared.

IV. INSTRUCTIONS ON THE ANTI-KICKBACK STATUTE

(To Be Read After the Close of Evidence)

INSTRUCTION NO. 13: The Anti-Kickback Statute: Introduction

The Anti-Kickback Statute is a law enacted by Congress to combat fraud and abuse against federal healthcare programs, like Medicare and Medicaid.[6] This statute prohibits knowingly and willfully offering, paying, soliciting, or receiving anything of value in exchange for recommending the purchasing or ordering of goods paid for by federal healthcare programs, including Medicare and Medicaid. Any person or entity that offers or gives kickbacks, and any party that solicits or receives kickbacks, in connection with a federal healthcare program violates the Anti-Kickback Statute.

In this case, Plaintiffs allege that Novartis and eight specialty pharmacies knowingly and willfully entered into arrangements that violated the Anti-Kickback Statute when the pharmacies sought reimbursement from Medicare and Medicaid for Exjade or Myfortic they dispensed. Specifically, the Anti-Kickback Statute makes it illegal to:

1. Knowingly and willfully offer or pay any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to recommend purchasing or ordering any good or item for which payment may be made in whole or in part by Medicare or Medicaid; and/or

2. Knowingly and willfully solicit or receive any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind in return

[6] *United States v. Borrasi*, 639 F.3d 774, 781 (7th Cir. 2011); *see also United States v. Gerber*, 760 F.2d 68, 70-71 (3rd Cir. 1985) (noting that the Anti-Kickback Statute was amended in 1977 because "Congress [was] concerned with the growing problem of fraud and abuse in the [healthcare] system," including a "particular concern [with] the practice of giving 'kickbacks'"); H. R. Rep. No. 95–393, pt. 2, at 44 (1977) (explaining the need to strengthen the Anti-Kickback Statute to address the "disturbing degree of fraudulent and abusive practices associated with the provision of health services financed by the medicare and medicaid programs").

for recommending purchasing or ordering any good or item for which payment may be made in whole or in part by Medicare or Medicaid.

For purposes of this trial, Novartis's relationship with a specialty pharmacy violated the Anti-Kickback Statute if there was an arrangement between Novartis and the pharmacy whereby Novartis knowingly and willfully offered something of value to the pharmacy to induce the pharmacy to recommend the purchase or ordering of a Novartis drug, and if the pharmacy knowingly and willfully agreed to receive the thing of value from Novartis in return for recommending the purchase or order of the Novartis drug.

Source: 42 U.S.C. § 1320a-7b(b); *United States v. Borrasi*, 639 F.3d 774, 781 (7th Cir. 2011); *United States v. Gerber*, 760 F.2d 68, 70-71 (3rd Cir. 1985); H. R. Rep. No. 95–393, pt. 2, at 44 (1977).

INSTRUCTION NO. 14: The Anti-Kickback Statute Elements

To establish that the relationship between Novartis and a specialty pharmacy violated the Anti-Kickback Statute, the Plaintiffs must prove that it was more likely than not that:

1. Novartis offered and/or provided "remuneration" to that specialty pharmacy;
2. with at least one purpose of inducing the pharmacy to recommend the purchase or ordering of Exjade or Myfortic;[7]
3. the pharmacy agreed to the offer of remuneration in return for recommending the purchase or order of Exjade or Myfortic; and
4. Novartis and the pharmacy acted knowingly and willfully.[8]

I will now go through each element in more detail:

Remuneration: The first element asks whether Novartis offered and/or provided "remuneration" to a specialty pharmacy. "Remuneration" means "something of value."[9] For purposes of this trial, if you find that, as Plaintiffs allege, Novartis offered patient referrals and/or rebates to the pharmacies, then you must find that Novartis did offer "remuneration" as defined by the Anti-Kickback Statute. This is because it has been decided, as a matter of law, that both patient referrals and rebates are things of value.

Recommend: As part of the second element, you have to decide whether Novartis offered something of value to induce – a term that I will define for you in a moment – to "recommend" Exjade or Myfortic. You should give the term "recommend" its ordinary meaning and usage. Therefore, a person does not need to have the authority to prescribe a drug in order to recommend

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[7] *United States v. Rogan*, 459 F. Supp. 2d 692, 722 (N.D. Ill. 2006); *see also United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985); *United States v. Bay State Ambulance*, 874 F.2d 20, 30 (1st Cir. 1989).

[8] *U.S. ex rel. Kester v. Novartis Pharmaceuticals Corp.*, 23 F. Supp. 3d 242, 262-63 (S.D.N.Y. 2014) ("*Novartis I*").

[9] *United States v. Narco Freedom, Inc.*, --- F. Supp. 2d ----, 2015 WL 1499265, at *8 (S.D.N.Y. Apr. 2, 2015).

the purchasing or ordering of that drug. For example, pharmacists, nurses, or other personnel at a specialty pharmacy may make recommendations when they communicate with a patient, a patient's caretaker, a doctor or other prescriber, and say that a Novartis drug is beneficial. They also may make recommendations when they advise a patient, or the patient's caretaker, that the patient should order the drug or a refill of the drug from the pharmacy, and when they suggest to a doctor or other prescriber that a drug should be prescribed.[10]

Inducement: For purposes of this trial, to "induce" means that Novartis intended for the patient referrals or the rebates it offered or provided to a specialty pharmacy to influence the pharmacy's decision to recommend the purchasing or ordering of Exjade or Myfortic.[11]

You can find that the "inducement" element is satisfied if any purpose that Novartis had, in offering or providing patient referrals and/or rebates to a specialty pharmacy, was to influence the pharmacy to recommend the purchase or ordering of Exjade or Myfortic.[12] If Plaintiffs show that it was more likely than not that one purpose of Novartis's offer of rebates and patient referrals

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[10] *United States v. Polin*, 194 F.3d 863, 866-67 (7th Cir. 1999); HHS OIG, Special Fraud Alert, 94 Fed. Reg. 31,157 (Dec. 19, 1994) (payments to pharmacies implicate the anti-kickback statute if "one purpose of any of these marketing schemes is to induce the provision of a prescription drug item reimbursable by Medicaid").

[11] *United States v. Lahue*, 261 F.3d 993, (10th Cir. 2001) (affirming use of jury instruction where "induce" defined as the intent to gain influence over the reason or judgment of a person making referral decisions); *United States v. Mathur*, 2012 UWL 4742833, at *10 (D. Nev. Sept. 13, 2012) ("[F]or purposes of the Anti-Kickback Act, the term 'induce' means 'an intent to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business"); *United States ex rel. Osheroff v. Tenet Healthcare Corp.*, 2012 WL 2871264, at *8 (S.D. Fla. July 12, 2012) (same).

[12] *Rogan*, 459 F. Supp. 2d at 722; *Greber*, 760 F.2d at 72 ("If the payments were intended to induce the physician to use Cardio-Med's services, the statute was violated, even if the payments were also intended to compensate for professional services."); *Bay State Ambulance*, 874 F.2d at 30 ("The issue of the sole versus primary reason for payments is irrelevant since *any* amount of inducement is illegal") (emphasis in original); *United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000) (adopting one-purpose test set forth in *Greber*); *see also United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998) (if remuneration was offered at least in part to induce referrals, element met); *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989) (affirming jury instruction with "one purpose" language); OIG Advisory Opinion No. 99-2 (Feb. 26, 1999) ("The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to obtain money for referral of services or to induce further referrals"); OIG Advisory Opinion 99-13 (Nov. 30, 1999) (same).

was to induce the recommendation of the purchase or ordering of Exjade or Myfortic, you should consider the inducement element met, even if there may have been other purposes behind offering or providing the referrals and/or rebates. It is not a defense that there may have been other reasons for the referrals and/or rebates.[13]

"In Return For": The third element asks whether, as part of its relationship with Novartis, a pharmacy agreed to recommend Exjade or Myfortic in return for the offer of patient referrals and/or rebates from Novartis. Here, Plaintiffs do not have to show that the pharmacy recommended the drug in a specific way in return for the patient referrals or rebates, that the pharmacy made a specific number of recommendations, or that the pharmacy was successful in terms of getting patients or prescribers to follow its recommendations. Plaintiffs only need to show that the pharmacy had an understanding with Novartis that it would make favorable recommendations about Exjade or Myfortic in return for the offer of patient referrals or rebates from Novartis.

Knowingly and Willfully: Finally, the fourth element is whether Novartis and a specialty pharmacy "knowingly and willfully" engaged in a relationship that violated the Anti-Kickback Statute. Here, Plaintiffs only need to show that it was more likely than not that Novartis and the pharmacy were aware that their actions were wrongful or unlawful. The Plaintiffs do not need to

[13] *Greber*, 760 F.2d at 70-72 (noting that when Congress amended the Act in 1977 to deter "the growing problem of fraud and abuse in the system," it added a proscription against the payment of "remuneration," which contemplates the rendering of a service, whereas the predecessor statute merely prohibited payment of "kickbacks," for which no service is rendered and concluding that the "one purpose" test is consistent with Congressional intent"); *Bay State Ambulance*, 874 F.2d at 30 ("The gravamen of Medicare Fraud is inducement. Giving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare payments towards a particular recipient."); *McClatchey*, 217 F.3d 823; *Kats*, 871 F.2d at 108.

establish that Novartis or the pharmacy knew about the Anti-Kickback Statute or specifically intended to violate that law.[14]

Sources: See citations provided in footnotes, *supra*.

[14] All circuits addressing this issue, except the Ninth Circuit (whose ruling on this issue has since been abrogated by statute), have held that to violate the AKS the defendant need only know that his conduct was generally wrongful. *See, e.g.*, *United States v. Starks*, 157 F.3d 833, 837-39 (11th Cir. 1998) (knowledge of the statute is not required for an AKS violation); *Davis*, 132 F.3d at 1094 (same); *Bay State Ambulance*, 874 F.2d at 33 (same); *United States v. Jain*, 93 F.3d 436, 439-41 (8th Cir. 1996) (same). Congress explicitly remedied the Ninth Circuit's erroneous injection of a specific intent requirement on March 23, 2010, when it amended the AKS to eliminate any confusion about whether specific intent was required. *See* Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub.L. 111-148, Title IV, § 6402(f)(2), effective March 23, 2010 (codified at 42 U.S.C. § 1320a-7b(h)). This amendment provides that "[w]ith respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section." Therefore, any Novartis conduct occurring after March 23, 2010, is expressly not subject to a specific intent requirement. Notably, Congress took this action to correct the Ninth Circuit's erroneous interpretation of the earlier law, which had improperly injected a specific intent requirement into the statute. Congress specifically noted, in passing the PPACA amendment to the AKS, that it "addresses confusion in the case law over the appropriate meaning of 'willful' conduct in healthcare fraud…. [T]he Ninth Circuit Court of Appeals has read the term to require proof [of specific intent, which] is inappropriate…. [The bill] clarifies that 'willful conduct' in this context does not require [specific intent]. As a result, health care fraudsters will not receive special protection they don't deserve." 155 Cong. Rec. S10852, S10853 (Oct. 28, 2009) (Statement of Senator Kaufman to the Committee on the Judiciary on behalf of himself and Senators Leahy, Specter, Kohl, Schumer, and Klobuchar).

INSTRUCTION NO. 15: Corporate Conduct

Plaintiffs allege that Novartis and pharmacies engaged in illegal kickback relationships. Novartis is a corporation. A corporation does not act on its own, but can only act through its officers, employees, or agents. Therefore, Novartis is responsible for the unlawful acts of its officers, employees, and agents, even if those acts were against corporate policy, provided those acts were done within the scope of the officer's, employee's, or agent's authority and for Novartis's benefit. This will usually be the case if an act is done in the ordinary course of a person's employment or within the scope of the corporation's business.

For purposes of this trial, if you find that an employee, agent, or officer of Novartis violated the Anti- Kickback Statute and, as I will instruct you in a moment, the False Claims Act, you must find that Novartis violated the Anti-Kickback Statute and the False Claims Act.

Sources: *FJPI* § 108.1; *see also Grand Union Co. v. United States*, 696 F.2d 888, 891 (11th Cir. 1983); *United States v. Hangar One, Inc.*, 563 F.2d 1155 (5th Cir. 1977); *United States v. Ridglea State Bank*, 357 F.2d 495 (5th Cir. 1965). *Cf. United States v. O'Connell*, 890 F.2d 563 (1st Cir. 1989) (employer was liable for FCA violations based on conduct of employee, even though employee was acting only for his own benefit).

INSTRUCTION NO. 16: Discount Safe Harbor

Novartis contends that its relationships with the Exjade and/or Myfortic specialty pharmacies did not violate the Anti-Kickback Statute because those relationships fall within the "discount safe harbor." Novartis bears the burden to prove this contention by a preponderance of the evidence; and it must do so by showing that every element of the safe harbor requirements is satisfied.[15]

At the outset, let me clarify one issue about where this contention applies and where it does not apply. As you have heard, Plaintiffs allege that, with respect to Exjade, Novartis offered and provided both patient referrals and so-called rebates to specialty pharmacies. As a matter of law, there is no safe harbor for patient referrals; and you should not consider Novartis's contention about the discount safe harbor in relation to the patient referrals.

The discount safe harbor may apply to a rebate offered by Novartis if Novartis shows that, *first*, its rebate offer to a pharmacy was a discount in substance; *second*, that all of the specific requirements of the discount safe harbor are satisfied; and, *third*, that the relationship was at "arms' length." If Novartis does not make each of these showings, then the discount safe harbor does not apply.

First, a rebate is covered by the discount safe harbor only if Novartis is offering a lower price to induce a pharmacy to purchase a drug, and not in return for the pharmacy to perform some service like contacting physicians or patients to recommend that they prescribe or order the drug.[16]

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[15] *See United States v. Shaw*, 106 F. Supp. 2d 103, 122 (D. Mass. 2000); *United States v. Norton*, 17 Fed. Appx. 98, 102 (4th Cir. 2001) (district court properly declined to provide jury instructions regarding Safe Harbor where the written agreement at issue did not meet the seven requirements of the personal service Safe Harbor and defendant failed to present sufficient evidence of this affirmative defense).

[16] 42 C.F.R. § 1001.952(h)(5) ("For purposes of this paragraph, the term discount means a reduction in the amount a buyer . . . is charged for an item or service based on an arms-length transaction [and excludes] Services provided in accordance with a personal or management services contract . . . ."); HHS OIG *Medicare and State Health Care Programs: Fraud and Abuse;*

To decide whether a rebate was offered by Novartis to a pharmacy as a genuine price concession or in return for some service, you have to look at the substance of the transaction, and not simply how Novartis labelled the payment.[17] Here, you should consider whether the discounts and rebates were a "price concession" made to encourage the pharmacies to buy Novartis' products, or whether they were actually payments that Novartis made to the pharmacies in exchange for their performing a service for Novartis, such as to recommend a Novartis drug to someone else. If they were payments for a service, they are not true discounts or rebates and do not qualify for the discount safe harbor. [18]

Second, if you consider the rebates Novartis offered to a specialty pharmacy to be a true "price concession," then you must evaluate the evidence to determine whether the discount or rebate meets four additional requirements of the "discount" safe harbor:

OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,958 (July, 29, 1991) ("The remuneration in a discount is merely a lowered price that a purchaser would otherwise obtain from a seller, which is made as an inducement to purchase larger quantities); *cf.* 42 C.F.R. § 1001.952(d) (entirely separate safe harbor for payments made for "services").

[17] *United States v. Shaw*, 106 F. Supp. 2d 103, 115-16 (D. Mass. 2000) (rejecting defendant's argument "that any discount, "properly disclosed and appropriately reflected", is exempt from criminal liability" because "[w]hat makes the activity illegal is not the label someone attaches to the form of the transaction, even if the form may give rise to the rebuttable inference of illegality. The reason behind the transaction and the requisite state of mind underlying the criminal act are more significant than form and label"); *see also U.S. ex rel. Lisitza v. Johnson & Johnson*, 765 F. Supp. 2d 112, 125 (D. Mass. 2011) (where rebates used to pay for recommendations, safe harbor not met); *OIG Anti-Kickback Provisions*, 56 Fed. Reg. at 35,958 (in evaluating whether a transaction involves prohibited remuneration, "the fundamental analysis" must be based on the recognition "that the substance rather than simply the form of a transaction should be controlling").

[18] *U.S. ex rel. Banigan v. Organon USA Inc.*, 883 F. Supp. 2d 277, 296 (D. Mass. 2012) (holding that safe harbor does not apply to arrangements labeled as "discounts" by drug-maker where payments in fact were offered in exchange for the pharmacy's agreement to recommend drugs as part of a product conversion scheme); *Lisitza*, 765 F. Supp. 2d at 125 (same); *see also* HHS OIG *Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions under the Anti-Kickback Statute*, 64 Fed. Reg. 63,518, 63,530 ("there may be arrangements that do not fit the definition [of discount] where access to a seller's favorable discount rates is itself an inducement or reward for referrals").

(a) If the discount is in the form of a "rebate," then the terms of the rebate were fixed and disclosed in writing to the buyer (*i.e.*, the pharmacy) at the time of the first sale, to the pharmacy, to which that rebate would apply.

(b) Novartis fully and accurately reported the rebate on the invoice, coupon or statement submitted to the pharmacy.

(c) Novartis informed the pharmacy in a manner reasonably calculated to give notice to the pharmacy of the pharmacy's obligations to report the rebate to the government and to provide information to the government upon request; and

(d) Novartis did not do anything that would impede the pharmacy from meeting its obligation to provide information to the government, upon request, about the rebates.[19]

If you find that Novartis's rebate relationship with a specialty pharmacy failed to comply with any of these requirements, then the discount safe harbor does not apply to that relationship. For example, if you find that Novartis failed to fix any term of its relationship with a pharmacy and disclose it in writing, then Novartis cannot qualify for the discount safe harbor.[20]

Third, to qualify for the discount safe harbor, Novartis also must show that its relationships with the Exjade and Myfortic specialty pharmacies were "arms-length."[21] An arms-length transaction is one in which the dealings between the parties are not collusive, and in which no oneparty has undue influence over the other. Therefore, if you find that Novartis's relationship with a specialty pharmacy was collusive or involved undue influence, then you should find that the relationship was not at arms' length and the discount safe harbor therefore does not apply.

Sources: See citations provided in footnotes, *supra*.

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[19] 42 C.F.R. §§ 1001.952 (h)(1)(iii)(A), (h)(2)(ii)(A), and (h)(2)(ii)(B).

[20] *Lisitza*, 765 F. Supp. 2d at 124-125 (holding that discount safe harbor does not apply where "the terms and conditions of [rebate] payment were not" fully disclosed).

[21] 42 C.F.R. § 1001.952(h)(5); *see also Banigan*, 883 F. Supp. 2d at 296 (rejecting application of the discount safe harbor because a relationship between drug-maker and pharmacy involving "collateral kickbacks" was not an arms-length transaction).

V. THE FALSE CLAIMS ACT

INSTRUCTION NO. 17: False Claims Act: Background

As you heard at the start of this trial, Plaintiffs have sued Novartis under a federal law called the False Claims Act and similar laws of various states. The federal False Claims Act authorizes the United States Government to recover from anyone who knowingly presents, or knowingly causes others to present, false or fraudulent claims for the payment of Government funds. The purpose of the False Claims Act is to make the United State whole in the event of a false claim and to deter fraud against the Government.

The states in this case have laws similar to the federal False Claims Act. Unless I instruct you otherwise, the same conduct that violates the federal False Claims Act also violates state false claims act laws. After I instruct you on federal law, I will then explain the ways in which the laws of some states differ.

Sources: 31 U.S.C. §§ 3729-3733; S. Rep. No. 99-345, 4, 14 (July 28, 1986), *reprinted in* 1986 U.S.C.C.A.N. 5266; *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968); FJPI § 178:10.

INSTRUCTION NO. 18: Summary of False Claims Act provisions

The False Claims Act provides, in relevant part, that "any person who … knowingly … causes to be presented a false or fraudulent claim for payment or approval" or who "knowingly … causes to be made or used, a false record or statement material to a claim" is liable to the United States Government. In addition, anyone who conspires to do either of those things is also liable to the United States.

Source: 31 U.S.C. §§ 3729(a)(1)-(3) & (a)(1)(A)-(C).

INSTRUCTION NO. 19: Elements of Violation of 31 U.S.C. § 3729(a)(1) and (a)(1)(A) as amended

Plaintiffs argue that Novartis has violated three different provisions of the False Claims Act, which I will refer to as sections 3729(a)(1)(A), (a)(1)(B), and (a)(1)(C). Let me begin with section 3729(a)(1)(A). Here, Plaintiffs allege that Novartis entered into kickback relationships with specialty pharmacies and thereby caused the claims that the pharmacies submitted to Medicare and Medicaid for reimbursement for Exjade or Myfortic to be false.

Specifically, for you to find Novartis liable under section 3729(a)(1)(A),[22] Plaintiffs must show that it was more likely than not:

One, that Novartis caused a false or fraudulent claim to be presented to Medicare or Medicaid for payment by a specialty pharmacy; and

Two, that Novartis knew the claim was false or fraudulent.

As I will explain to you in a moment, if you find that Novartis and a specialty pharmacy entered into a kickback arrangement in violation of the Anti-Kickback Statute, then the claims that the pharmacy submitted to Medicare and Medicaid for Exjade or Myfortic were false as a matter of law. This is because, by submitting the reimbursement claims for Exjade or Myfortic, the pharmacy was representing to the government that it had not agreed to any offer of kickbacks from Novartis in return for recommending Exjade or Myfortic.

Sources: 31 U.S.C. §§ 3729(a)(1) & (a)(1)(A); *U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 23 F. Supp. 3d 242, 252 (S.D.N.Y. 2014) ("*Novartis I*").

[22] The textual differences between the pre-amended 3729(a)(1) and the amended 3729(a)(1)(A) are irrelevant for instructions in this case, because Plaintiffs allege the submission of claims to federal healthcare programs.

INSTRUCTION NO. 20: Claim Defined

As used in the False Claims Act, a "claim" is any request or demand for money where the United States Government provides any portion of the money requested.

As relevant to this trial, it has been decided, as a matter of law, that any claim that a specialty pharmacy submitted to Medicare or Medicaid for dispensing Exjade or Myfortic is a "claim" under the False Claims Act.

Source: 31 U.S.C. § 3729(b)(2)(A)(ii)(I).

INSTRUCTION NO. 21: False Claims Act: Caused To Be Submitted

The False Claims Act is violated not only by a person who submits a false claim, but also by one who causes another to submit a false claim. In determining whether Novartis, by offering or paying kickbacks to a specialty pharmacy, caused the specialty pharmacy to submit a false claim, you should decide whether Novartis' conduct was a "substantial factor" in making the pharmacy's claims false and whether the pharmacy's submission of the false claims to Medicare or Medicaid was "foreseeable" to Novartis, or, in other words, a "normal consequence" of Novartis' conduct.

Sources: *U.S. ex rel. Bunk v. Birkart Globistics GmbH & Co.*, 2011 WL 5005313, at *7 n. 10 (E.D. Va. Oct. 19, 2011) (quoting jury instruction on "Cause False Claim to Be Filed"); *see also U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242-245 (3rd Cir. 2004) (applying "substantial factor" and "normal consequence" test); *U.S. ex rel. Feldman v. City of New York*, 808 F. Supp. 2d 641, 650 (S.D.N.Y. 2011) (citing *Zimmer* with approval); *U.S. ex rel. Freedman v. Suarez-Hoyos*, 2012 WL 4344199, at *8 (M.D. Fla. Sept. 21, 2012) (applying "substantial factor" and "normal consequence" test)

INSTRUCTION NO. 22: False Claims Act/Anti-Kickback Statute: False or Fraudulent Claim

For you to find a False Claims Act violation, you must find that Novartis's conduct rendered false at least one claim that was submitted to Medicare and Medicaid.

Plaintiffs allege that Novartis offered or paid something of value to specialty pharmacies to induce the pharmacies to recommend Exjade and Myfortic, and that consequently, the pharmacies submitted false claims to Medicare or Medicaid for payment for those drugs. If you find that Novartis did offer or pay something of value to a specialty pharmacy, and that one of the purposes for this was to induce the pharmacy to recommend Exjade or Myfortic, then you must find that any claims submitted by the specialty pharmacy to Medicare or Medicaid for payment for those drugs were "false" or "fraudulent" claims under the False Claims Act.

Sources: 42 U.S.C. § 1320a-7b(g) (2010); *Novartis IV*, 41 F. Supp. 3d 323, 329-331; *Novartis I*, 23 F. Supp. 3d 242, 252; *Novartis V*, 2014 WL 4401275, at *9-10; *U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 2015 WL 109934, at *15-20 (S.D.N.Y. Jan. 6, 2015) ("*Novartis VII*").

INSTRUCTION NO. 23: False Claims Act: Definition Of "Knowingly"

For purposes of the alleged False Claims Act violations, the term "knowing" and "knowingly" mean that the Defendant, with respect to information:

(1) had actual knowledge of the information; or

(2) acted in deliberate ignorance of the truth or falsity of the information; or

(3) acted in reckless disregard of the truth or falsity of the information.

Plaintiffs do not need to prove that Novartis and the specialty pharmacies intended to defraud the government.

Source: 31 U.S.C. § 3729(b)(1)(A).

INSTRUCTION NO. 24: Actual Knowledge and Reasonable Inquiry

The Plaintiffs may establish that Novartis had actual knowledge through circumstantial evidence. For example, if Plaintiffs present persuasive evidence that a certain condition existed for a substantial period of time, and that Novartis had regular opportunities to observe the condition, then you may draw the inference that Novartis had knowledge of the condition.

If it appears from the evidence in the case that Novartis had information which would lead a reasonably prudent person to make an inquiry through which he would surely learn certain facts, then Novartis may be found to have had actual knowledge of these facts, the same as if Novartis had made such inquiry and had actually learned such facts.
The law expects a person to make a reasonable inquiry under the circumstances and will charge a person with notice and knowledge of whatever he would have learned upon making such inquiry.

Sources: *U.S. ex rel. Taylor v. Gabelli*, 345 F. Supp. 2d 313, 330 (S.D.N.Y. 2004); *U.S. ex rel. Ervin and Associates, Inc. v. Hamilton Securities Group, Inc.*, 370 F. Supp. 2d 18, 41 (D.D.C. 2005) (defendant must make "such inquiry as would be reasonable and prudent to conduct under the circumstances to ascertain the true and accurate basis of the claim"); *U.S. ex rel Stone v. Rockwell Intern. Corp.*, 282 F.3d 787, 811-812 (10th Cir. 2002) (affirming validity of jury instruction directing jury that in considering whether defendant knowingly made any false statements, it "must consider all direct and circumstantial evidence").

INSTRUCTION NO. 25: Deliberate Ignorance

I instructed you that the term "knowingly" can mean that Novartis acted with deliberate ignorance as to the truth or falsity of the information. The United States can prove "deliberate ignorance" through proof that Novartis deliberately closed its eyes to what would otherwise have been obvious to it. A finding that Novartis purposely avoided learning all the facts or suspected a fact but refused to confirm it, also constitutes deliberate ignorance. Stated another way, Novartis's knowledge of a fact may be inferred from willful blindness to the existence of the fact. It is entirely up to you as to whether you find any deliberate closing of the eyes and the inference to be drawn from any such evidence.

Sources: *U.S. ex rel. K & R Ltd. Partnership v. Mass. Housing Finance Agency*, 456 F.Supp.2d 46, 61 (D.D.C. 2006); *U.S. ex rel. Ervin and Associates, Inc. v. Hamilton Securities Group, Inc.*, 370 F.Supp.2d 18, 41 (D.D.C. 2005).

INSTRUCTION NO. 26: Reckless Disregard

I also instructed you that the term "knowingly" includes acting in "reckless disregard" of an act's truth or falsity. The term "reckless" means acting with an indifference to the consequences. If Novartis caused a pharmacy to submit a claim without properly considering the claim's truth or falsity, then Novartis may be found to have acted in reckless disregard of the truth or falsity of that claim. Similarly, if, in connection with a claim to Medicare or Medicaid, Novartis used or made a statement or caused a pharmacy to make or use a statement without properly considering the statement's truth or falsity, then Novartis may be found to have acted in reckless disregard of the truth or falsity of that statement.

Sources: Jury Instructions given in *U.S. ex rel. Drakeford, v. Toumey*, 3:05-cv-2858-MBS, (D.S.C.) [Dkt. 810];[23] *see generally United States v. Krizek*, 111 F.3d 934, 942 (D.C. Cir. 1997); *U.S. ex rel. Ervin and Associates, Inc. v. Hamilton Securities Group, Inc.*, 370 F. Supp. 2d 18, 41 (D.D.C. 2005).

[23] Also available at: http://www.americanbar.org/content/dam/aba/administrative/healthlaw/tuomey_jury_Instructions.authcheckdam.pdf.

INSTRUCTION NO. 27: Corporate Knowledge

Defendant Novartis is a corporation. The law regards corporations as separate entities or persons having the capacity to sue and be sued. Corporations may only act through natural persons, such as their directors, officers, employees, or other agents. The law, therefore, charges Novartis with the knowledge that comes to each of its agents through the performance of his or her respective duties. Novartis is held to have the knowledge that comes to it through its various officers, employees, or agents.[24]

[24] *Frank v. Dana Corp.*, 646 F.3d 954, 963 (6th Cir. 2011) (imputing corporation with knowledge of CEO and CFO and discussing cases).

INSTRUCTION NO. 28: Elements of Violation of § 3729(a)(1)(B) as amended

Plaintiffs also allege that Novartis violated section 3729(a)(1)(B) of the False Claims Act. To prove this claim, the Plaintiffs must show that it was more likely than not that:

(1) Novartis caused a specialty pharmacy to make or use a false record or statement;

(2) The statement was material to a false claim to Medicare or Medicaid; and

(3) Novartis acted knowingly.

To find Novartis liable on this claim, you need to find a false statement or record and a false claim.[25] The false statement also needs to be material to the false claim.

First, in terms of the false statement or record, Plaintiffs allege that Novartis knowingly used, or caused the specialty pharmacies to use, several different types of false statements. Let me give you two examples. First, Plaintiffs have offered enrollment forms and contracts in which the specialty pharmacies stated or certified to Medicare or Medicaid that they were in compliance with the Anti-Kickback Statute, or with all "applicable" laws (of which the AKS is one). If you find that a pharmacy was violating the AKS while making or using on the statement or certification of compliance, then you can find that Plaintiffs have proved the use of a false statement. Second, Plaintiffs have offered into evidence a Corporate Integrity Agreement that Novartis signed in 2010, as well as annual reports certifying compliance with that agreement. If you find that Novartis did not comply with the conditions it agreed to in that agreement, then that is another instance where a false statement.

[25] As the Second Circuit has held, the 2009 amendment to 31 U.S.C.§ 3729(a)(2) is retroactive, so only the amended statute, § 3729 (a)(1)(B) (2009), is relevant. *See Novartis I*, 23 F. Supp. 3d at 251 (citing *U.S. ex rel. Kirk v. Schindler Elevator Corp.*, 601 F.3d 94, 113 (2d Cir. 2010), *rev'd on other grounds*, 131 S. Ct. 1885 (2011)).

Second, in terms of the false claims, as I explained to you previously, if you find that Novartis and a specialty pharmacy engaged in a kickback relationship, then the Medicare and Medicaid claims submitted by that pharmacy during the course of the relationship are false as a matter of law.

Finally, what does the term "material" mean? A statement is material to a claim if the statement has a natural tendency to influence, or be capable of influencing, whether the claim is paid.

Sources: 31 U.S.C. §§ 3729(a)(1)(B) and 3729(b)(4); *Novartis I*, 23 F. Supp. 3d at 352.

INSTRUCTION NO. 29: Elements of Violation of 31 U.S.C. § 3729(a)(3), (a)(1)(C) as amended

Third, Plaintiffs also argue that Novartis is liable for conspiracy. For the Plaintiffs to prevail on this claim, they must establish by a preponderance of the evidence that:

(1) There was a conspiracy, that is, an agreement, between Novartis and a specialty pharmacy;

(2) That an object of the conspiracy was either:

a. to present a false or fraudulent claim for payment or approval, or

b. to make or use a false record or statement material to a false or fraudulent claim; and

(3) That one or more conspirators performed an overt act in furtherance of the conspiracy.

Source: *Novartis II*, 41 F. Supp. 3d at 328 (listing elements).[26]

[26] As relevant to this trial, there is no difference between the pre-2009 amendment language of § 3729(a)(3) and the post-amendment language of § 3729(a)(1)(C). Specifically, Novartis and the specialty pharmacies knew that the claims for payment at issue in this case were to be paid by federal healthcare programs.

INSTRUCTION NO. 30: Conspiracy Explanations

To show a conspiratorial agreement, the Plaintiffs are not required to prove that two or more people entered into a solemn pact, but only that two or more persons explicitly or implicitly came to an understanding to achieve the specified unlawful object, whether or not they were successful. It is not necessary for the Plaintiffs to prove that the conspiracy lasted throughout the entire period that pertained to the object of their conspiracy, but only that it existed for some time within that period.

The existence of a conspiracy may be established by circumstantial evidence. You may conclude that someone joined a conspiracy even in the absence of evidence directly showing an express or formal agreement. Rather, you may infer that an agreement existed from any collection of circumstances tending to show a mutual understanding, spoken or otherwise, that the members would cause to have a fraudulent claim paid by the government.

Finally, the third element of the conspiracy claim is whether that some member of the conspiracy, not necessarily Novartis, knowingly and willfully committed an overt act in furtherance of the conspiracy. An "overt act" is any act knowingly committed by one of the conspirators, in an effort to accomplish some object or purpose of the conspiracy. The overt act must tend toward accomplishment of the plan or scheme and must be knowingly, done and in furtherance of some object or purpose of the conspiracy alleged in the complaint.

INSTRUCTION NO. 31: Co-Conspirators Statements: Common Plan Or Scheme

The Court has admitted into evidence against Novartis the acts and statements of others, because these acts and statements were committed by persons alleged to be confederates or co-conspirators of Novartis.

If you find that Novartis was a member of the conspiracy, then any act or statement by any member of the conspiracy made in furtherance of the conspiracy may be considered against Novartis. This is so even if the acts were done and the statements were made in Novartis's absence and without Novartis's knowledge. On the other hand, if the acts were done or the statements were made by someone whom you did not find was a member of the conspiracy, or if they were not done or said in furtherance of the conspiracy, they may be considered by you only as evidence against the person who said or did them.

INSTRUCTION NO. 32: Liability Of Co-Conspirator

A party can be a participant in a conspiracy even though it does not participate in all of the acts that may take place under the conspiracy. A participant in a conspiracy needs to know the essentials of the conspiracy, but it need not know all the details. It is liable for the acts of its coconspirators done in furtherance of the conspiracy even if it had no knowledge of the acts that were carried out as long as those acts were reasonably foreseeable. Once liability for conspiracy under the False Claims Act is established, each conspirator is liable for each of the overt acts committed pursuant to the conspiracy and for the damages arising from the conspiracy even if it did not personally commit all of the acts that may take place under the conspiracy.

INSTRUCTION NO. 33: Damages Not an Element

A showing of damages to the government is not an element of a cause of action under the provisions of the False Claims Act that I have just described. Accordingly, you need not find that the United States actually suffered a measurable loss in order to find that the defendant violated the False Claims Act.

Sources: 31 U.S.C. § 3729; *U.S. ex rel. Bunk v. Gosselin World Wide Moving, N.V.*, 741 F.3d 390, 405 (4th Cir. 2013); *United States v. Neifert-White Co.*, 390 U.S. 228, 231-33 (1968); *U.S. ex rel. Bahrani v. Conagra, Inc.*, 465 F.3d 1189, 1203 (10th Cir. 2006); *Varljen v. Cleveland Gear Co.*, 250 F.3d 426, 429 (6th Cir. 2001); *United States v. Hughes*, 585 F.2d 284, 286 n. 1 (7th Cir. 1978).

INSTRUCTION NO. 34: Benevolent Motivation Not A Defense

The United States need not provide evidence of a motive to establish a violation of the False Claims Act. Thus, benevolent motivation is not a defense, nor is it a legal justification, to a case brought under the False Claims Act.

VI. INSTRUCTIONS REGARDING STATE FALSE CLAIMS ACTS

A. General State Instructions

INSTRUCTION NO. 35: Background

As I have told to you, 11 states have joined this lawsuit against Novartis. These states have sued Novartis under their False Claims Acts, other statutes, or the common law. In addition, the Relator, Mr. Kester, has brought claims against Novartis on behalf of over a dozen additional states and the District of Columbia under their False Claims Acts. Those statutes allow a Relator like Mr. Kester to bring a lawsuit on behalf of a state government. The fact that a state is represented by the Relator, instead of its own attorneys, should have no bearing on the decisions you make in this case.[27]

[27] *See, e.g., U.S. ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1360 n.17 (11th Cir. 2006) (noting that "[i]n any given case, the government may have a host of reasons for not pursuing a claim"); *U.S. ex rel. Chandler v. Cook County*, 277 F.3d 969, 974 n.5 (7th Cir. 2002) ("There is no reason to presume that a decision by the Justice Department not to assume control of the suit is a commentary on its merits. The Justice Department may have myriad reasons for permitting the private suit to go forward including limited prosecutorial resources and confidence in the relator's attorney."); *U.S. ex rel. DeCarlo v. Kiewit/AFC Enterprises*, 937 F. Supp. 1039, 1047(S.D.N.Y. 1996) ("Non-intervention does not necessarily signal governmental disinterest in an action . . . .").

INSTRUCTION NO. 36: States are Plaintiffs

In these instructions I will refer to the States that are plaintiffs in this case. For purposes of these instructions, you should consider the District of Columbia to be one of those States.

INSTRUCTION NO. 37: Federal Instructions Apply

Earlier, I gave you instructions about the federal Anti-Kickback Statute. Those instructions also apply to the States' claims. Each of the states operates a Medicaid program with state and federal funds.[28] As a result, the federal Anti-Kickback Statute is one of the laws that is applicable to those Medicaid programs.[29]

INSTRUCTION NO. 38: State False Claims Acts

Most States' False Claims Acts are modeled on the federal False Claims Act and have very similar or identical provisions. These state False Claims Acts impose liability on a corporation that:

- "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval"
- "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;" or
- "conspires to commit" one of the above violations[30]

[28] Stipulated Facts, JPTO, ECF No. 472 at ¶¶ 18-20.
[29] Memorandum and Order, *U.S. ex rel. Kester v. Novartis*, Dkt. No. 227 at 23 (Novartis IV).
[30] 31 U.S.C. § 3729(a)(1)(A), (B) and (C); see O.C.G.A. § 49-4-168.1(a)(1)–(3); 740 Ill. Comp. Stat. § 175/3(a)(1)(A)–(C); Ind. Code 5-11-5.5-2(b)(1)–(2),(7)–(8); Md. Code, Health - General, § 2-602(a)(1)–(3); Mich. Comp. Laws § 400.603(1)–(2), 400.606(1); N.J. Rev. Stat. § 2A:32C-3(a)–(c); N.Y. Fin. Law § 189(a)–(c); 63 Okla. Stat. tit. § 5053.1(B)(1)–(3); Wis. Stat. § 20.931(2)(a)–(c); Cal. Gov. Code § 12651(a)(1)–(3); Colo. Rev. Stat. 25.5-4-305(1)(a), (b) and (g); Conn. Gen. Stat. § 4-275(a)(1), (2) and (3); Del. Code Ann. tit. 6, § 1201(a)(1), (2) and (3);

Therefore, if, after following my earlier instructions, you found that Novartis violated a provision of the federal False Claims Act as a result of its transactions with specialty pharmacies relating to Exjade or Myfortic, you must also find that Novartis violated the analogous provisions of all of the States' False Claims Acts,[31] except the Texas False Claims Act.

Additionally, if you find that Novartis violated a provision of State law, a State regulation or a State policy upon which payment was conditioned, you must also find that Novartis violated that State's False Claims Act.[32]

D.C. Code § 2-381.02(a)(1), (2) and (7); Fla. Stat. Ann. § 68.082(2)(a), (b) and (c); Haw. Rev. Stat. § 46-171(a)(1), (2) and (8); La. Rev. Stat. Ann. § 46:438.3(A), (B) and (D); Mass. Gen. Laws ch. 12, § 5B(a); Minn. Stat. § 15C.02(a)(1), (2) and (3); Mont. Code Ann. § 17-8-403 (1)(a), (b) and (c); Nev. Rev. Stat. § 357.040(1)(a), (b) and (i); N.C. Gen. Stat. § 1-607(a)(1), (2) and (3); R.I. Gen. Laws § 9-1.1-3(a)(1), (2) and (3); Tenn. Code Ann. § 71-5-182(a)(1)(A), (B), and (C); Va. Code Ann. § 8.01-216.3(A)(1), (2) and (3).

[31] Although there are some differences between the States' definition of "claim" in their respective False Claims Acts, there is no dispute between the parties that the claims for Exjade and Myfortic that the specialty pharmacies submitted to the States' Medicaid program were claims for purposes of the States' False Claims Acts. *See* Novartis' Contentions, JPTO, ECF No. 472 at 37-96. Similarly, although some States' False Claims Acts only apply to their Medicaid programs while others' apply more generally, these distinctions have no bearing on the parties' contentions in this case. *Id.* Further, while Oklahoma's False Claims Act prohibits the use of false records or statements "to get" a false or fraudulent claim paid, any differences from statutes prohibiting the use of false records or statements "material" to a false or fraudulent claim are not relevant to this case. *Id.*

[32] Cal. Welf. & Inst. Code § 14107.2(a); Cal. Welf. & Inst. Code § 14107.2(b); Cal. Welf. & Inst. Code § 14107.11(a)(2); Georgia Part I Policies and Procedures for Medicaid/Peachcare for Kids Manual, Part I, Section 106(E); Illinois Vendor Fraud and Kickback statute, 305 ILCS 5/8A-3; False Reporting and Other Fraudulent Activities, Ill. Admin. Code tit. 89 § 140.35; Ind. Code § 12-15-24; N.J.S.A. 30:4D–17(c); Mich. Comp. Laws. § 400.604; New York, 18 N.Y.C.R.R. § 515.2(b), § 518.1(c), Soc. Serv. Law § 366-d; Okla. Stat. Title 56 §§ 1002, 1005(A)(6); and Wis. Stat. § 49.49(2) (recodified to 946.91(3) April 10, 2014).

B. Texas False Claims Act

INSTRUCTION NO. 39: Texas False Claims Act

Texas is the one state in this case that has a False Claims Act that is significantly different than the federal False Claims Act. For Texas, you will need to determine whether Novartis is liable under its False Claims Act. In doing so, you should follow the instructions I gave in connection with the federal False Claims Act, except as modified by the instructions I will now give to you:

For **Texas' False Claims Act**, Novartis is liable if you find that, by a preponderance of the evidence, the Plaintiffs have established either that:

i) Novartis knowingly caused a pharmacy to make a false statement or misrepresentation of a material fact to permit the pharmacy to receive a benefit or payment under the Medicaid program that is not authorized,[33] or

ii) Novartis knowingly violated the Texas anti-kickback law. The Texas anti-kickback law makes it illegal to offer or pay, directly or indirectly, overtly or covertly any remuneration, including any kickback, bribe, or rebate, in cash or in kind to induce a pharmacy to purchase, lease, or order, or arrange for or recommend the purchase, lease, or order of, any good, facility, service, or item for which payment may be made, in whole or in part, under Texas Medicaid.[34]

You should interpret the term "knowingly" as used above to mean that Novartis either:

i) had knowledge of the information;

ii) acted with conscious indifference to the truth or falsity of the information; or

[33] Tex. Hum. Res. Code § 36.002(6)(A).
[34] Tex. Hum. Res. Code §§ 36.002(13) and 32.039(b)(1-e).

iii) acted in reckless disregard of the truth or falsity of the information.[35] Proof of Novartis' specific intent to commit one of the acts set forth above is not required.[36]

You should interpret the term "material" as in "material fact" to mean: "having a natural tendency to influence or to be capable of influencing."[37]

You should bear in mind that a pharmacy that is violating the federal AKS of the Texas anti-kickback law is "not authorized" to bill Texas Medicaid.[38]

VII. INSTRUCTIONS REGARDING OTHER STATE LAWS

A. General Instructions on Other State Laws

INSTRUCTION NO. 40: Other State Laws

In addition to False Claims Act claims, some of the States have sued Novartis under other state laws. These claims only relate to Novartis' relationship with BioScrip concerning Exjade. I will now discuss those claims with you.

[35] Tex. Hum. Res. Code § 36.0011(a)(1)-(3).
[36] *Id*.
[37] Tex. Hum. Res. Code § 36.001(5-a).
[38] *Novartis V*, 43 F. Supp. 3d 332 at 364 ("[F]rom and after March 2010 'the act of submitting a claim for reimbursement itself implie[d] compliance with' the AKS); 1 TAC 354.1801(h) (Claims are subject to post-payment review for compliance with state and federal laws and regulations and HHSC policy. Reimbursement paid to a pharmacy provider for claims that do not comply may be subject to recoupment of overpayment.)

VIII. ILLINOIS-SPECIFIC JURY INSTRUCTIONS

INSTRUCTION NO. 41: Illinois Public Assistance Fraud: Nature of the Claim

Illinois alleges that Novartis created an arrangement with BioScrip where the latter received kickbacks in the form of patient referrals and rebates in exchange for encouraging orders of the drug Exjade. Thus, the claims BioScrip submitted to the Illinois Medical Assistance Program for Exjade were tainted by those kickbacks, and Novartis caused BioScrip to submit such false claims. By virtue of submitting claims tainted by kickbacks, BioScrip submitted false statements or representations to the State in violation of Illinois' Public Assistance Fraud statute because BioScrip had agreed to abide by applicable federal and state laws and regulations when submitting their certifications to become a billing provider under the Illinois Medical Assistance Program.

INSTRUCTION NO. 42: Illinois Public Assistance Fraud, 305 Ill. Comp. Stat. Ann. 5/8A-7(b): Elements of the Violation

Illinois' Public Assistance Fraud statute provides that it shall be unlawful for any person, firm, corporation, association, agency, institution or other legal entity, other than an individual recipient, to willfully, by means of a false statement or representation, or by concealment of any material fact or by other fraudulent scheme or device on behalf of himself or others, obtain or attempt to obtain benefits or payments under this Code to which he or it is not entitled.

To sustain its burden of proof that Novartis violated 5/8A-7(b) of the Illinois Public Assistance Code, Illinois must prove the following elements by a preponderance of the evidence:

(1) Novartis made a false statement or representation, or concealed a material fact, or engaged in a fraudulent scheme or device on behalf of itself or others;

(2) Novartis used that false statement or representation or concealed material fact or fraudulent scheme or device to obtain benefits under the Illinois Public Assistance Code;

(3) Novartis engaged in such conduct willfully.

If the State has proven, by a preponderance of the evidence, the elements of the above violation, your verdict will be for the State on this count.

INSTRUCTION NO. 43: Illinois False Statement or Fraudulent Scheme

In your consideration of the first element that Novartis made or used a false record or statement, there is no requirement that Novartis submitted the false record directly to Illinois' Medical Assistance Program. [39] In this case, Illinois alleges that the certifications signed by BioScrip were false statements because the Pharmacies submitted claims tainted by kickbacks while at the same time agreeing to abide by applicable laws when submitting their claims.

[39] *See U.S. ex rel. Fahner v. Alaska*, 591 F. Supp. 794, 799-800 (N.D. Ill. 1984) (stating that the Illinois statute closely tracks the Federal False Claims Act); *U.S. ex rel. Luther v. Consol. Indus., Inc.*, 720 F. Supp. 919, 922 (N.D. Ala. 1989) (finding that false claims presented indirectly via contractors does not prevent recovery under the federal false claims statute) citing *Murray & Sorenson, Inc. v. U.S.*, 207 F.2d 119, 123 (1st Cir. 1953).

INSTRUCTION NO. 44: Illinois Willful or Willfully

The term "willful or willfully" means the same as "knowing or knowingly," as defined by the Federal False Claims Act.[40] "Knowing or knowingly" mean that a person, with respect to information:

(1) has actual knowledge of the information;

(2) acts in deliberate ignorance of the truth or falsity of the information; or

(3) acts in reckless disregard of the truth or falsity of the information.

Illinois is not required to prove that Novartis acted with the specific intent to defraud.

INSTRUCTION NO. 45: Illinois Public Assistance Fraud: Attempting to Obtain or Obtaining Payments Under The Illinois Public Assistance Code

In your consideration of Illinois' Public Assistance Fraud claim, you will have to determine whether Novartis obtained payments under the Illinois Public Aid Code. For purposes of this claim, a person, including a corporation, has attempted to obtain or has obtained payments under the Illinois Public Aid Code when the claim for payment is submitted through participation in the Illinois Medical Assistance Program.[41] To find a violation of Illinois' Public Assistance Fraud statute, it is not a requirement that you find that Novartis received payment directly from the Illinois Medical Assistance Program.[42] It is sufficient for purposes of that law, if Novartis

[40] *See U.S. ex rel. Fahner v. Alaska*, 591 F. Supp. at 799-800 (stating that the Illinois statute closely tracks the Federal False Claims Act).
[41] *See* 305 ILCS 5/5-16.4 (establishing the Medical Assistance Provider Payment Fund from which the State Comptroller issues warrants to providers)
[42] *See U.S. ex rel. Fahner v. Alaska*, 591 F. Supp. 794, 799-800 (N.D. Ill. 1984) (stating that the Illinois statute closely tracks the Federal False Claims Act); see also *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F.Supp. 2d 12,15-16 (D. Mass. May 8, 2010)

received public funds indirectly through sales of Exjade. In this case, Illinois claims that as a result of Novartis' kickback arrangement with BioScrip, Novartis attempted to obtain and did obtain payment under the Illinois Public Aid Code through sales of Exjade to BioScrip that were reimbursed by Illinois' Medical Assistance Program.

INSTRUCTION NO. 46: Damages Under the Illinois Public Assistance Fraud Statute

The measure of the State of Illinois' damages under its Public Assistance Fraud Statute is the amount that it paid out by reason of the false statements over and above what it would have paid if the claims had been truthful.

INSTRUCTION NO. 47: Civil Penalties Under the Illinois Public Assistance Fraud Statute

If you find that Novartis willfully presented or caused BioScrip to present false statements or engage in a fraudulent scheme to receive payment from the State of Illinois, Novartis will be liable for civil penalties. The Illinois Public Assistance Fraud Statute provides for specific civil penalties for each false or fraudulent claim paid by the state of Illinois.[43]

IX. INDIANA-SPECIFIC JURY INSTRUCTIONS

INSTRUCTION NO. 48: Indiana Crime Victims Relief Act: Nature of the Claim

Indiana alleges that Novartis, having created an arrangement with BioScrip where BioScrip received kickbacks in the form of patient referrals and rebates in exchange for encouraging orders of the drug Exjade that were reimbursed by Indiana's Medicaid program,

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(holding that the defendant, a drug manufacturer, still violated the Federal False Claims Act by causing false claims to be presented for payment), citing United States ex rel. Marcus v. Hess, 317 U.S. 537, 544-45 (1943).

[43] 305 Ill. Comp. Stat. Ann. 5/8A-7

committed one or more crimes against Indiana. The Indiana Crime Victims Relief Act provides that if a person suffers a pecuniary loss as a result of a violation of Ind. Code 35-43, he may bring a civil action against the person who caused the loss for damages.[44] Indiana alleges it suffered pecuniary losses as a result of violations of two sections of Ind. Code 35-43 by Novartis – those violations being Theft, Ind. Code § 35-43-4-2, and Medicaid Fraud, Ind. Code § 35-43-5-7.1.

INSTRUCTION NO. 49: Indiana Crime Victims Relief Act: Elements and Burden of Proof

Under the Indiana Crime Victims Relief Act, the elements necessary to establish a violation are those found in the criminal statutes.[45] To sustain its burden of proof, Indiana must prove by a preponderance of the evidence all of the elements of the alleged crimes, including the requisite criminal intent.[46] "An actual criminal conviction is not required for recovery" … [and the statute] "does not require criminal charges or proof beyond reasonable doubt."[47]

INSTRUCTION NO. 50: Basis of Indiana Criminal Liability: Aiding, Inducing, or Causing an Offense

Under Indiana law, a person who knowingly aids, induces, or causes another person to commit an offense commits that offense, even if the other person has not been prosecuted for the offense.[48] Accomplice liability applies to the contemplated offense and all acts that are a probable and natural consequence of the concerted action.[49] To assign accomplice liability to Novartis, Indiana must show by a preponderance of the evidence that:

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[44] Ind. Code §34-24-3-1.
[45] *Lambert v. Yellowbird, Inc.*, 496 N.E.2d 406, 410 (Ind. Ct. App.) decision clarified on denial of reh'g, 498 N.E.2d 80 (Ind. Ct. App. 1986).
[46] *Gordon v. Bank of New York Mellon Corp.*, 964 F. Supp. 2d 937, 943 (N.D. Ind. 2013).
[47] *Wysocki v. Johnson*, 18 N.E.3d 600, 606 (Ind. 2014).
[48] Ind. Code § 35-41-2-4.
[49] *Tuggle v. State*, 9 N.E.3d 726, 736 (Ind. Ct. App.) *transfer denied*, 14 N.E.3d 44 (Ind. 2014).

First, that Novartis knowingly offered kickbacks to BioScrip to induce it to encourage patients to order of Exjade;

Second, by offering kickbacks to BioScrip Novartis aided, induced, or caused BioScrip to commit Theft, in violation of Ind. Code § 35-43-4-2, or Medicaid Fraud, in violation of Ind. Code § 35-43-5-7.1 when BioScrip submitted its claims for reimbursement to the Indiana Medicaid program.

INSTRUCTION NO. 51: Basis of Indiana Criminal Liability: Culpability - Knowingly

A person engages in conduct "knowingly" if, when he engages in the conduct, he is aware of a high probability that he is doing so.[50] You are permitted to infer whether Novartis acted knowingly from the surrounding circumstances.[51]

INSTRUCTION NO. 52: Indiana Theft: Elements of an Offense

The State of Indiana alleges that Novartis, having created an arrangement with BioScrip where BioScrip received kickbacks in the form of patient referrals and rebates in exchange for encouraging orders of the drug Exjade that were reimbursed by Indiana's Medicaid program, committed Theft, in violation of Ind. Code §35-43-4-2. To prevail on its claim under the Indiana Crime Victims Relief Act with respect to allegations that Indiana suffered pecuniary damages as a result of violations of Ind. Code §35-43-4-2, Indiana must prove by a preponderance of the evidence that:

First, Novartis knowingly aided, induced, or caused BioScrip to exert unauthorized control over the property of the State of Indiana; and

[50] Ind. Code § 35-41-2-2(b)
[51] *Markland v. State*, 865 N.E.2d 639, 643 (Ind. Ct. App. 2007).

Second, Novartis intended to deprive the State of Indiana a part of the value or use of its property.

INSTRUCTION NO. 53: Indiana Theft: First Element

With respect to the first element, "exert control over property" means to obtain, take, carry, or possess property.[52] "A person's control over property of another person is "unauthorized" if it is exerted: (1) Without the other person's consent; (2) in a manner or to an extent other than that to which the other person has consented; … (4) By creating or confirming a false impression in the other person…"[53]

If you find that Novartis knowingly aided, induced or caused BioScrip to obtain property from the State of Indiana by submitting reimbursement claims for Exjade that resulted from the receipt of kickbacks by BioScrip from Novartis, thus receiving payments in a manner other than that to which the State of Indiana has consented or that Novartis aided, induced, or caused BioScrip to create or confirm a false impression that BioScrip was submitting such claims and was in compliance with all applicable laws and regulations, such as the Federal and State Anti-Kickback statues, then you may find that Novartis exerted unauthorized control over the property of the State of Indiana.

INSTRUCTION NO. 54: Indiana Theft: Second Element

With respect to the second element, the Indiana Anti-Kickback Statute, Ind. Code § 12-15-24-1 provides that evidence that a person or provider received money or other benefits as a result of a violation of a provision of Article 15 or a rule established the Secretary of the Indiana Family and Social Services Administration under Article 15, constitutes *prima facie* evidence that the person or provider intended to deprive the state of a part of the value of the money or

[52] Ind. Code § 35-43-4-1.
[53] *Id.*

other benefits. A Medicaid provider who solicits, offers, or receives a kickback in connection with the furnishing of goods or services to a Medicaid recipient commits a misdemeanor violation of a provision of Article 15.[54] "'*Prima facie*' means such evidence as is sufficient to establish a given fact and which will remain sufficient if uncontradicted."[55]

If you find by a preponderance of the evidence that Novartis paid kickbacks to BioScrip in the form of patient referrals and rebates in exchange for encouraging orders of the drug Exjade that were reimbursed by Indiana's Medicaid program and if you find that Novartis has not rebutted the presumption that such kickbacks were intended to deprive the state of a part of the value of the money or other benefits paid by the state to BioScrip, then you may find that Novartis intended to deprive the State of Indiana a part of the value or use of its property.

INSTRUCTION NO. 55: Indiana Medicaid Fraud: Elements of an Offense

Under Indiana law, a person who knowingly obtains payment from the Medicaid program by means of a false or misleading statement or other means commits Medicaid Fraud, a misdemeanor, unless the fair market value of the offense is at least seven hundred fifty dollars ($750), in which case the offense would be a felony.[56]

If you find that Novartis, as a result of providing BioScrip kickbacks in the form of patient referrals and rebates in exchange for encouraging orders of the drug Exjade that were reimbursed by Indiana's Medicaid program, aided, induced, or caused BioScrip to falsely certify that BioScrip was in compliance with all applicable Federal and State laws, you may find that Novartis aided, induced, or caused BioScrip to obtain payment from the Indiana Medicaid program by means of a false or misleading statement or other means.

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[54] Ind. Code § 12-15-24-2.
[55] *Mullins v. State*, 646 N.E.2d 40, 50 (Ind. 1995).
[56] Ind. Code § 35-73-5-7.1.

X. MARYLAND-SPECIFIC JURY INSTRUCTIONS

INSTRUCTION NO. 56: Maryland Burden of Proof -- Clear and Convincing Evidence for Fraud or Deceit

Maryland has asserted a claim of fraud or deceit in this case. A party who contends fraud on the part of another has the burden of proving the claim by clear and convincing evidence. This burden of proof requires more than a preponderance of the evidence but less than proof beyond a reasonable doubt.

To be clear and convincing, evidence should be "clear" in the sense that it is certain, plain to the understanding, and unambiguous and "convincing" in the sense that it is so reasonable and persuasive as to cause you to believe it.[57]

INSTRUCTION NO. 57: Maryland Fraud or Deceit

To recover damages for deceit, it must be shown that:

(1) the defendant made a false representation of a material fact;

(2) the defendant knew of its falsity or made it with such reckless indifference to the truth that it would be reasonable to charge the defendant with knowledge of its falsity;

(3) the defendant intended that the plaintiff would act in reliance on such statements;

(4) plaintiff did justifiably rely on the representations of the defendant; and,

(5) plaintiff suffered damages as a result of that reliance.[58]

[57] Maryland Civil Pattern Jury Instructions, 11:9.
[58] Maryland Civil Pattern Jury Instructions, 11:11.

INSTRUCTION NO. 58: Maryland False Representation -- Defined

A false representation is a statement, conduct or act by which one intentionally misleads another person about a material fact.

A statement of opinion, judgment, prediction of a future event or promise may constitute false representation of a material fact.

A promise to do something may be a false representation if the person did not intend to do the promised act when the promise was made.[59]

INSTRUCTION NO. 59: Maryland Non-Disclosure or Concealment

To recover damages for deceit it must be shown:

(1) that defendant intentionally concealed a material fact that he or she had a duty to disclose;

(2) with the intent to induce the plaintiff to act differently from how the plaintiff would have acted had he or she known the true facts;

(3) that because of the concealment the plaintiff acted in a manner different from how he or she would have acted had the plaintiff known the true facts; and

(4) plaintiff suffered damages as a result of that reliance.[60]

INSTRUCTION NO. 60: Maryland Material Fact -- Defined

A fact is material if under the circumstances a reasonable person would rely upon it in making his or her decision.

[59] Maryland Civil Pattern Jury Instructions, 11:13.
[60] Maryland Civil Pattern Jury Instructions, 11:12.

A fact may also be material, even though a reasonable person might not regard it as important, if the person stating or concealing it knows that the person with whom he or she is dealing probably will use the fact in determining his or her course of action.[61]

INSTRUCTION NO. 61: Maryland Punitive Damages -- Generally

If you find for the plaintiff and award damages to compensate for the injuries (losses) suffered, you may go on to consider whether to make an award for punitive damages. A claim for punitive damages must be proved by clear and convincing evidence.

An award for punitive damages should be:

(1) In an amount that will deter the defendant and others from similar conduct.

(2) Proportionate to the wrongfulness of the defendant's conduct and the defendant's ability to pay.

(3) But not designed to bankrupt or financially destroy a defendant.[62]

XI. NEW YORK-SPECIFIC PROPOSED JURY INSTRUCTIONS

INSTRUCTION NO. 62: N.Y. Soc. Serv. Law Section 145-b: General Statement of the Violation

New York's Social Services Law Section 145-b provides that it shall be unlawful for any person, including a corporation, knowingly, by means of a false statement or representation or by deliberate concealment of any material fact or any other fraudulent scheme or device on behalf of itself or others to attempt to obtain or to obtain payments from public funds for supplies furnished to the Medicaid program.[63]

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[61] Maryland Civil Pattern Jury Instructions, 11:14.
[62] Maryland Civil Pattern Jury Instructions, 10:13.
[63] N.Y. Soc. Serv. Law § 145-b(1).

To sustain its burden of proof that Novartis violated Section 145-b of the Social Services Law, New York must prove the following elements by a preponderance of the evidence:

First, New York must show that Novartis engaged in false or fraudulent conduct as that conduct is set out in the statute. New York must show that Novartis made or used a false statement or misrepresentation, or caused a false record or statement to be made or used, or engaged in a deliberate concealment, or used any other fraudulent scheme or device.

Second, New York must show that Novartis engaged in such false or fraudulent conduct to attempt to obtain or to obtain payment from public funds.

Third, New York must show that Novartis engaged in such conduct knowingly.

INSTRUCTION NO. 63: N.Y. Soc. Serv. Law § 145-b:
False or Fraudulent Conduct

In your consideration of the first element that Novartis made or used a false record or statement, there is no requirement that Novartis submitted the false record directly to New York's Medicaid program.[64] In this case, New York alleges that BioScrip or its predecessor companies submitted certifications to New York's Medicaid program stating that it would comply with applicable federal and state laws and regulations were false once BioScrip entered into a kickback relationship with Novartis.

INSTRUCTION NO. 64: N.Y. Soc. Serv. Law § 145-b:
Attempting to Obtain or Obtaining Public Funds

In your consideration of New York's Social Services Law claim, you will have to determine whether Novartis obtained public funds from New York's Medicaid program. For purposes of this claim, a person, including a corporation, has attempted to obtain or has obtained public funds when any portion of the funds from which payment was attempted or obtained come, directly or indirectly, from public funds.[65] To find a violation of New York's Social Services Law, it is not a requirement that you find that Novartis received public funds directly from the New York Medicaid program.[66] It is sufficient for purposes of that law, if Novartis received public funds indirectly through sales of Exjade. In this case, New York claims that as a

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[64] *See People v. Brooklyn Psychosocial Rehab. Inst.*, 185 A.D.2d 230, 234, 585 N.Y.S.2d 776, 779 (1992) (concluding that where defendant made false statements that resulted in public payments that "inured to [his] benefit," though indirectly, he obtained public funds within meaning of Section 145-b); *In Re Pharm. Industry Average Wholesale Price Litig.*, 685 F. Supp. 2d 186, 202 (D. Mass. 2010) (holding defendants' false pricing reports to publishing compendia were the basis for N.Y.'s claims under Soc. Serv. Law § 145-b).

[65] N.Y. Soc. Serv. Law. § 145-b(c).

[66] *People v. Brooklyn Psychosocial Rehabilitation Institute*, 185 A.D.2d 230, 234-35 (2d Dept. 1992) (defendant enriched himself when the provider used funds collected from Medicaid to pay grossly inflated rents to a company owned by defendant's family); *In Re Pharm. Industry Average Wholesale Price Litig.*, 685 F. Supp. 2d 186, 204 (D. Mass. 2010).

result of Novartis's kickback arrangement with BioScrip, Novartis attempted to obtain and did obtain public funds through sales of Exjade to BioScrip that were reimbursed by New York's Medicaid program.

INSTRUCTION NO. 65: N.Y. Soc. Serv. Law § 145-b: Knowledge

For purposes of New York's Social Services Law claim, a person acts knowingly with respect to conduct or the circumstances described in that statute when he is aware that his conduct is of such nature or that such circumstance exists.[67] To determine whether Novartis acted knowingly, you may consider the conduct of its employees and all of the circumstances surrounding that conduct, including, but not limited to, what they did, said, or wrote.

A person's knowledge may be proved by circumstantial evidence, and the objective evidence of the surrounding circumstances of its conduct. A defendant's knowledge may be inferred from all of the circumstances shown by the evidence.

INSTRUCTION NO. 66: Elements of New York's Claim under Executive Law Section 63-c

New York seeks restitution under Executive Law Section 63-c.

To prevail in its claim under Executive Law § 63-c, New York must prove the following elements by a preponderance of the evidence:

First, that New York has identified money, funds, credits or other property that the State held or owned,

[67] N.Y. Soc. Serv. Law § 145-b; N.Y. Soc. Serv. Law § 145; N.Y. Penal Law § 15.05(2); CJI2d [NY] Culpable Mental States—Knowingly.

Second, that Novartis obtained, received, converted or disposed of such property; and Third, that Novartis obtained, received, converted or disposed of such property without right.

INSTRUCTION NO. 67: First Element of New York's Claim under Exec. Law § 63-c: State Property

With respect to the first element, it is undisputed in this action that New York's Medicaid program used state money to pay claims for Exjade dispensed by BioScrip.[68]

[68] New York's Medicaid program provides prescription drug coverage for eligible individuals and families and pays claims for prescription drugs submitted by Medicaid providers; see also 42 U.S.C. § 1396 et seq. It has long been recognized that the Attorney General may sue to recover overpayments by the Medicaid program under Executive Law § 63-c. *State v. Belt Parkway Nursing Home*, 95 Misc. 2d 264, 268 (Sup. Ct. Kings Cnty. 1978).

INSTRUCTION NO. 68: Second Element of New York's Claim under Exec. Law § 63-c

With respect to the second element, there is no requirement that New York show that Novartis received money directly from the state.[69]

INSTRUCTION NO. 69: Third Element of N.Y.'s Claim under Executive Law § 63-c: Without right

With respect to the third element, a person or corporation receives money or property without right if the State has a legal or equitable claim to such money or property.[70] If you find that Novartis offered kickbacks to BioScrip and induced it to encourage patients to order Exjade that were purchased from Novartis and billed to New York's Medicaid program, then you may find that Novartis received money or property of New York State without right.

INSTRUCTION NO. 70: New York's Claim under Executive Law § 63-c: Recovery

If you find that Novartis received money or property of New York State without right, it is for you to determine the amount of money that Novartis should return to New York. The amount that Novartis should return is the amount of payments of Medicaid funds to BioScrip for false or fraudulent Exjade claims.

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[69] New York may recover under Executive Law § 63-c from defendants who improperly obtained money derived from Medicaid payments. *See Ferran*, 77 A.D.3d at 701 (defendants held liable for Medicaid overpayments where defendants obtained kickbacks from Medicaid providers in exchange for referring patients).

[70] The State may recover pursuant to any viable action at law or in equity. *Grecco*, 21 A.D.3d at 477; *Ferran*, 77 A.D.3d at 701.

XII. OKLAHOMA'S PROPOSED JURY INSTRUCTIONS

INSTRUCTION NO. 71: Oklahoma's Claims

Oklahoma has asserted claims for violations of the Oklahoma Medicaid Program Integrity Act and Civil Conspiracy.

INSTRUCTION NO. 72: Oklahoma Burden of Proof- Greater Weight of the Evidence

For Oklahoma's Medicaid Program Integrity Act claims, the greater weight of the evidence means that the proposition on which such party has the burden of proof is more probably true than not true. The greater weight of the evidence does not mean the greater number of witnesses testifying to a fact, but means what seems to you more convincing and more probably true.

INSTRUCTION NO. 73: Oklahoma Burden of Proof – Clear and Convincing Evidence

For Oklahoma's Common Law Fraud and Civil Conspiracy claims clear and convincing evidence means that you must be persuaded, considering all the evidence in the case, that the proposition on which the party has this burden of proof is highly probable and free from serious doubt.[71]

INSTRUCTION NO. 74: Violation of the Oklahoma Medicaid Program Integrity Act

The State of Oklahoma alleges that Novartis violated Section 1005(A)(1) of the Oklahoma Medicaid Program Integrity Act. If a violation of this section has occurred, Novartis is liable to the State for damages, penalties, and interest.[72]

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[71] OUJI 3d (Rev. 2009) 3.2.
[72] 56 O.S. (1989) § 1007(A) and (B).

In order for the State of Oklahoma to sustain its burden of proof as to Section 1005(A)(1), the State must prove the following elements[73] by the greater weight of the evidence:

First, Novartis is a "person" who willfully and knowingly;

Second, made or caused to be made a claim;

Third, Novartis knew the claim to be false, in whole or in part;

Fourth, by commission or omission.

If you find that the State of Oklahoma sustained its burden, then your verdict will be for the State. If you find that the State of Oklahoma did not prove all of the elements listed above, then your verdict will be for Novartis.

INSTRUCTION NO. 75: Violation of the Oklahoma Medicaid Program Integrity Act Elements

The State of Oklahoma alleges that Novartis violated Section 1005(A)(6) of the Oklahoma Medicaid Program Integrity Act, 56 O.S. (1999) § 1005. If a violation of this section has occurred, Novartis is liable to the State for damages, penalties, and interest.[74]

In order for the State of Oklahoma to sustain its burden of proof as to Section 1005(A)(6), the State must prove the following elements[75] by the greater weight of the evidence:

First, Novartis is a "person" who willfully and knowingly;

Second, solicited or accepted a benefit, pecuniary benefit, or kickback;

Third, in connection with goods or services paid, or claimed by a provider to be payable, by the Oklahoma Medicaid Program.

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[73] 56 O.S. (1999) § 1005(A)(1).
[74] 56 O.S. (1989) § 1007(A) and (B).
[75] 56 O.S. (1999) § 1005(A)(4).

If you find that the State of Oklahoma sustained its burden, then your verdict will be for the State. If you find that the State of Oklahoma did not prove all of the elements listed above, then your verdict will be for Novartis.

INSTRUCTION NO. 76: Violation of the Oklahoma Medicaid Program Integrity Act: Making a Claim

For purposes of the Oklahoma Medicaid Program Integrity Act, a person shall be deemed to have made or caused to be made a claim, statement, or representation if the person:

1. Had the authority or responsibility to make the **claim/statement/representation**, to supervise those who made the **claim/statement/representation**, or to authorize the making of the **claim/statement/representation**, whether by operation of law, business or professional practice, or office procedure; and
2. Exercised such authority or responsibility or failed to exercise such authority or responsibility and as a direct or indirect result, the false statement was made.[76]

INSTRUCTION NO. 77: Violation of the Oklahoma Medicaid Program Integrity Act: Definition of Claim

For purposes of the Oklahoma Medicaid Program Integrity Act, a "Claim" means a communication, including written, electronic, or magnetic, which is utilized to identify a good, item, or service as reimbursable pursuant to the Oklahoma Medicaid Program, or which states income or expense and is or may be used to determine a rate of payment pursuant to the Oklahoma Medicaid Program; and any application for payment by any person from the Oklahoma Medicaid Program or its fiscal agents for each good or service purported by any person to have been provided by any person to any Medicaid recipient.

[76] 56 O.S. (2000) § 1005(B).

INSTRUCTION NO. 78: Violation of the Oklahoma Medicaid Program Integrity Act: Definition of "Person"

For purposes of the Oklahoma Medicaid Program Integrity Act, it is not a requirement that you find that Novartis received funds directly from the Oklahoma Medicaid Program. It is sufficient for purposes of this law if Novartis received payment, indirectly through sales of Exjade. A "Person" is defined under this act as any Medicaid provider of goods or services or any employee of such provider, whether that provider is an individual, individual medical vendor, firm, corporation, professional association, partnership, organization, or other legal entity under the Oklahoma Medicaid Program, or any individual, individual medical vendor, firm, corporation, professional association, partnership, organization, other legal entity, or any employee of such who is not a provider under the Oklahoma Medicaid Program but who provides goods or services to a provider under the Oklahoma Medicaid Program for which the provider submits claims to the Oklahoma Medicaid Program or its fiscal agents.[77]

[77] 56 O.S. (1995) § 1002(8).

INSTRUCTION NO. 79: Violation of the Oklahoma Medicaid Program Integrity Act: Definition of "Provider"

For purposes of the Oklahoma Medicaid Program Integrity Act, a "Provider" means any person who has applied to participate or who participates in the Oklahoma Medicaid Program as a supplier of a good or a service.[78]

INSTRUCTION NO. 80: Violation of the Oklahoma Medicaid Program Integrity Act: Definition of "Knowing"

For purposes of the Oklahoma Medicaid Program Integrity Act, the terms "knowing" and "knowingly" are satisfied if you find that the person knew, or by virtue of the person's position, authority or responsibility, had reason to know, of the falsity of the claim, statement or representation. If so, then that person is deemed to have known that the claim, statement, or representation was false."[79]

INSTRUCTION NO. 81: Violation of the Oklahoma Medicaid Program Integrity Act: Definition of "Kickback"

For purposes of the Oklahoma Medicaid Program Integrity Act, a "kickback" means a return in any form by any individual, company, corporation, partnership, or association of a part of an expenditure made by a provider:

a) to the same provider,

b) to an entity controlled by the provider, or,

c) to an entity which the provider intends to benefit whenever such expenditure is reimbursed, or reimbursable, or claimed by a provider as

[78] 56 O.S. (1995) § 1002(9).
[79] 56 O.S. (1995) § 1005(D).

being reimbursable by the Oklahoma Medicaid Program and when the sum or value returned is not credited to the benefit of the Oklahoma Medicaid Program.

INSTRUCTION NO. 82: Oklahoma Common Law Fraud

The State of Oklahoma alleges that Novartis perpetrated a fraud on the State. In order to recover for common law fraud, the State of Oklahoma must prove by clear and convincing evidence the following:

1) That Novartis made a material misrepresentation,
2) The misrepresentation was false when it was made,
3) And was made as a positive assertion which Novartis either knew to be false or that Novartis made recklessly without knowledge of the truth,
4) with the intention that it be acted upon by the State of Oklahoma, and
5) which the State of Oklahoma relied on,
6) to the State of Oklahoma's detriment.[80]

If you find that the State of Oklahoma proved each of these elements, then your verdict will be for the State.

INSTRUCTION NO. 83: Oklahoma Civil Conspiracy

The State of Oklahoma alleges that Novartis entered into a conspiracy with the BioScrip to increase patient order refills by offering illegal rebates/kickbacks, in violation of the Federal

[80] *Bowman v. Presley*, 2009 OK 48, ¶ 13, 212 P.3d 1210, 1217-1218; *Howell v. Texaco, Inc.*, 2004 OK 92, ¶ 32, 112 P.3d 1154, 1161; *Varn v. Maloney*, 1973 OK 133, ¶ 17, 516 P.2d 1328, 1332; *Rucker v. Tietz*, 1962 OK 249, ¶ 16, 376 P.2d 341, 344; *Johnson v. Eagle*, 1960 OK 160, ¶ 6, 355 P.2d 868, 870.

and State Anti-Kickback Statutes. In order for the State of Oklahoma to recover for civil conspiracy to commit fraud, the State must prove, by clear and convincing evidence, the following:

First, that two or more persons or corporations entered into an agreement; [81]

Second, to do an unlawful act, or to do a lawful act by unlawful means; [82]

Third, that the conspirators pursued an independently unlawful purpose or used independently unlawful means; [83]

Fourth, and that act resulted in injury (damages) to the State of Oklahoma. [84]

If you find that the State of Oklahoma sustained its burden of proof by clear and convincing evidence,[85] then your verdict will be for the State and Novartis is liable for actual damages sustained by the State. If you find that the State of Oklahoma did not prove all of the elements listed above, then your verdict will be for Novartis.

XIII. WASHINGTON'S PROPOSED JURY INSTRUCTIONS

INSTRUCTION NO. 84: Background on Washington Fraudulent Practices Statute

Under Washington law, it is illegal for any person, including any corporation to "offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person…(b) to…arrange for or recommend purchasing…or ordering any goods, …service, or item for which payment may be

[81] *Shadid v. Monsour, et al.*, 746 P. 2d 685, 689 (Okla. Civ. App. 1987); *Roberson, et al. v. Painwebber, Inc., et al.*, 998 P.2d 193, 201 (Okla. Civ. App. 2000).
[82] *Brock v. Thompson*, 948 P.2d 279, 294 (Okla. 1997).
[83] *Id*.
[84] 746 P. 2d at 689.
[85] *Id* at 688.

made in whole or in part. . . ."[86] This statute was violated if Novartis induced BioScrip, in the form of patient referrals or rebates, to recommend Exjade to patients.

INSTRUCTION NO. 85: Washington Fraudulent Practices Statute, RCW 74.09.210(1)(a)

The State of Washington alleges that Novartis violated RCW 74.09.210(1)(a). If Novartis violated this statute, then it is liable to the State of Washington for damages and penalties. [87]

Under Washington law, a corporation that knowingly obtains or attempts to obtain Medicaid payments on behalf of itself or others, in a greater amount than that to which it is entitled by means of a willful false statement, is liable for the repayment of any excess Medicaid payments received.[88]

In this case, Washington alleges that Novartis offered kickbacks in the form patient referrals and/or rebates to BioScrip to induce it to recommend Exjade to patients and BioScrip accepted those kickbacks. In offering or paying these kickbacks, Novartis knowingly or recklessly obtained or attempted to obtain fraudulent payment for Exjade by inducing BioScrip to make willful false statements that the Exjade claims submitted by BioScrip were submitted in compliance federal and state law when in fact they were tainted by kickbacks. If you find that the State of Washington sustained its burden of proof by a preponderance of the evidence, then your verdict will be for the State. If you find that the State of Washington did not prove all of the elements listed above, then your verdict will be for Novartis.

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[86] RCW 74.09.240(2)(b)

[87] *See* Rev. Code Wash. Ann. § 74.09.210(2) (West 2015) (providing for civil penalties in an amount not to exceed three times the damages for a violation of Washington's Fraudulent Practices Statute).

[88] RCW 74.09.210(1)(a).

INSTRUCTION NO. 86: Washington Fraudulent Practices, RCW 74.09.210(1)(b)

The State of Washington alleges that Novartis violated RCW 74.09.210(1)(b). If Novartis violated this statute, then it is liable to the State of Washington for damages and penalties.

Under Washington law, a corporation that knowingly obtains or attempts to obtain Medicaid payments on behalf of itself or others, in a greater amount than that to which it is entitled, by willful misrepresentation, or by concealment of any material facts is liable for the repayment of any excess Medicaid payments received.[89]

In this case, Washington alleges that Novartis offered kickbacks in the form patient referrals and/or rebates to BioScrip to induce it to recommend Exjade to patients and BioScrip accepted those kickbacks. In offering or paying these kickbacks, Novartis knowingly or recklessly obtained or attempted to obtain fraudulent payment for Exjade by inducing BioScrip to willfully misrepresent or conceal the material fact that the Exjade claims submitted by BioScrip were tainted by kickbacks while at the same time BioScrip certified that when submitting such claims it would abide by federal and state law. If you find that the State of Washington sustained its burden of proof by a preponderance of the evidence, then your verdict will be for the State. If you find that the State of Washington did not prove all of the elements listed above, then your verdict will be for Novartis.

INSTRUCTION NO. 87: Washington Fraudulent Practices, RCW 74.09.210(1)(c)

The State of Washington alleges that Novartis violated RCW 74.09.210(1)(c). If Novartis violated this statute, then it is liable to the State of Washington for damages and penalties.

Under Washington law, a corporation that knowingly obtains or attempts to obtain Medicaid payments on behalf of itself or others, in a greater amount than that to which it is

[89] RCW 74.09.210(1)(b).

entitled by other fraudulent scheme or device is liable for the repayment of any excess Medicaid payments received.[90]

In this case, Washington alleges that Novartis offered kickbacks in the form patient referrals and/or rebates to BioScrip to induce it to recommend Exjade to patients and BioScrip accepted those kickbacks. In offering or paying kickbacks, Novartis knowingly or recklessly obtained or attempted to obtain, through BioScrip's submission of tainted claims, fraudulent payment for Exjade from the Washington Medicaid program. If you find that the State of Washington sustained its burden of proof by a preponderance of the evidence, then your verdict will be for the State. If you find that the State of Washington did not prove all of the elements listed above, then your verdict will be for Novartis.

INSTRUCTION NO. 88: Washington Tortious Interference with Business Expectation

The State of Washington alleges that Novartis tortiously interfered with a business expectation. Under Washington law, the State of Washington must prove five elements to establish a claim for tortious interference with a business expectancy:

(1) The existence of a valid contractual relationship between BioScrip and the State of Washington;

(2) That Novartis had knowledge of that relationship;

(3) That Novartis intentionally interfered, induced or caused BioScrip to breach the relationship;

(4) That Novartis interfered for an improper purpose or used improper means; and

(5) Resultant damages.[91]

[90] RCW 74.09.210(1)(c).

If you find that the State of Washington sustained its burden to prove each of these elements by a preponderance of the evidence, then your verdict will be for the State. If you find that the State of Washington did not prove all of the elements listed above, then your verdict will be for Novartis.[92]

INSTRUCTION NO. 89: Washington Civil Conspiracy

The State of Washington alleges that BioScrip and Novartis formed a civil conspiracy in which unlawful kickbacks were exchanged for Exjade referrals. Under Washington law, a civil conspiracy exists if two or more corporations combine to commit an unlawful act or to commit a lawful act by unlawful means or when two or more corporations combine by concerted action to accomplish an unlawful purpose or some purpose, not in itself unlawful, by unlawful means. In order to establish a conspiracy Plaintiff must show that the alleged conspirators entered into an agreement to accomplish the object of the conspiracy.[93] Your verdict will be for the State of Washington (on the claim of civil conspiracy) if you decide that the State of Washington has proved each of these elements by a clear, cogent, and convincing standard.

INSTRUCTION NO. 90: Washington Definitions of "Knowing" and "Knowingly"

For Washington's claims, "knowing" and "knowingly" mean that a person, with respect to information has actual knowledge of the information; acts in deliberate ignorance of the truth

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[91] *Commodore v. Univ. Mech. Contractors, Inc.*, 839 P.2d 314, 322 (Wash. 1992).
[92] WPI 352.01 Tortious Interference with Contract – Burden of Proof on the Issues – No Affirmative Defense (Modified).
[93] *Corbit v. J.I. Case Co.*, 70 Wash. 2d 522, 528-29. 424 P.2d 290 (Wash. 1967); *Wilson v. State of Washington*, 84, Wash. App. 332, 929 P.2d 448 (1996).

or falsity of the information or acts in reckless disregard of the truth or falsity of the information. "Knowing" and "knowingly" do not require proof of specific intent to defraud.[94]

INSTRUCTION NO. 91: Washington Definition of "Material"

For Washington's claims, "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.[95]

INSTRUCTION NO. 92: Washington Definition of "Willful"

For Washington's claims, a person acts willfully when he or she acts knowingly.[96]

INSTRUCTION NO. 93: Washington Liability of Corporations

Novartis is a corporation. A corporation can act only though its officers and employees. Any act or omission of an officer or employee is the act of omission of the corporation.[97]

INSTRUCTION NO. 94: Washington Burden of Proof

Because of the issues presented in this case, the State of Washington must meet different burdens of proof on the claims it makes. On the propositions of the RCW 74.09.210 Fraudulent Practices provisions and Tortious Interference with a Business Expectation, the State of Washington has the burden of proof by a preponderance of the evidence.

When it is said that a party has the burden of proof on any proposition, or that any proposition must be proved by a preponderance of the evidence, or the expression "if you find"

[94] RCW 74.66.010(7)(a).
[95] RCW 74.66.010(8).
[96] 11 WAPRAC WPIC I0.05 (3rd Ed.)
[97] WPI 50.18 Corporation Acts Through its Employees – No Issue as to Scope of Agency.

is used, it means that you must be persuaded, considering all the evidence in the case bearing on the question: whether Novartis, knowingly obtained or attempted to obtain Washington Medicaid payments on behalf of itself or others that it was not entitled to receive under any of the provisions of RCW 74.09.210, and/or intentionally interfered, induced or caused a breach of the contractual relationship between the Washington Medicaid program and BioScrip, that the proposition on which that party has the burden of proof is more likely true than not true.[98]

For the claims of Civil Conspiracy, the State of Washington has the burden of proving each of the elements of a Civil Conspiracy by clear, cogent, and convincing evidence. However, this burden of proof is applicable only to the proof of a Civil Conspiracy. All other allegations of the State of Washington must be proved by a preponderance of the evidence as that term is more fully defined previously.

Proof by clear, cogent, and convincing evidence means that the element must be proved by evidence that carries greater weight and is more convincing than a preponderance of evidence. Clear, cogent, and convincing evidence exists when occurrence of the element has been shown by the evidence to be highly probable. However, it does not mean that the element must be proved by evidence that is convincing beyond a reasonable doubt.[99]

[98] WAC 182-526-0485; WPI 21.01 Meaning of Burden of Proof – Preponderance of the Evidence.
[99] WPI 160.03 Fraud – Burden of Proof – Combined with Preponderance of the Evidence (modified).

XIV. AFFIRMATIVE DEFENSES

INSTRUCTION NO. 95: Burden of Proof: Affirmative Defenses

Novartis has asserted a number of affirmative defenses. An affirmative defense is an argument that, if true, will defeat the Plaintiffs' claims. Just as the United States has the burden of proving its claims by the preponderance of the evidence, Novartis has the burden of proving its affirmative defenses by the preponderance of the evidence. To establish a fact by a preponderance of the evidence is to prove that it is more likely so than not so. In other words, a preponderance of the evidence means that the evidence produces in your mind the belief that the thing in question is more likely true than not true.

Sources: *FPJI* § 101.01; *Sacks v. Franklin Covey, Co.*, 316 F.3d 337, 350 (2d Cir. 2003) (defining affirmative defenses)

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Respectfully submitted,

PREET BHARARA
United States Attorney
By: */s/ Li Yu*
LI YU
REBECCA C. MARTIN
DAVID J. KENNEDY
JEFFREY K. POWELL
PETER ARONOFF
Assistant United States Attorneys
86 Chambers Street, Third Floor
New York, New York 10007
Tel: (212) 637-2714

THE STATE OF CALIFORNIA
By its attorney,
Kamala Harris Attorney General

By: */s/ David B. Zlotnick*
David B. Zlotnick
Deputy Attorney General
Bureau of Medi-Cal Fraud and Elder Abuse
California Department of Justice
1455 Frazee Road, Ste. 315
San Diego, CA 92108
Phone: (619) 688-6043
Fax: (619) 688-4200
Email: Eliseo.Sisneros@doj.ca.gov

THE STATE OF GEORGIA
By its attorney, SAMUEL S. OLENS
Attorney General

By: */s/ Elizabeth White*
Elizabeth White
Assistant Attorney General
Georgia Medicaid Fraud Control Unit
200 Piedmont Avenue, S.E.
West Tower, 19th Floor Atlanta, GA 30334
Phone: (404) 656-4145
Fax: (404) 657-7441
Email: EWhite@law.ga.gov

THE STATE OF ILLINOIS
By its attorney, LISA MADIGAN
Attorney General

By: */s/ Elisa C. Hamilton*
Elisa C. Hamilton
Assistant Attorneys General
Office of the Illinois Attorney General
100 W. Randolph St., 13th Floor
Chicago, Illinois, 60601
Phone: (312) 814-2514
Fax: (312) 814-5366
Email: EHamilton@atg.state.il.us

THE STATE OF INDIANA
By its attorney,
Gregory F. Zoeller Attorney General

By: */s/ Lawrence J. Carcare II*
Lawrence J. Carcare II (Admitted *pro hac vice*)
Deputy Attorney General
Office of the Indiana Attorney General
Medicaid Fraud Control Unit
8005 Castleway Drive
Indianapolis, IN 46250-1946
Telephone: (317) 915-5319
Facsimile: (317) 232-7979
Email: Lawrence.Carcare@atg.in.gov

THE STATE OF MARYLAND
Brian E. Frosh
Attorney General of the State of Maryland

By: */s/Jennifer Forsythe*
Jennifer S. Forsythe, AAG
Office of the Attorney General
Medicaid Fraud Control Unit
200 St. Paul Street, 18th Floor
Baltimore, Maryland 21202
(410) 576-6864
jforsythe@oag.state.md.us
Attorneys for the State of Maryland

THE STATE OF MICHIGAN
By its attorney, BILL SCHUETTE
Attorney General

By: */s/ Deborah Harper*
Deborah Harper
Assistant Attorney General
Michigan Department of Attorney General
Phone: (517) 241-6500
Fax: (517) 241-6515
Email: HarperD3@michigan.gov

THE STATE OF NEW JERSEY
By its attorney,
JOHN JAY HOFFMAN
Acting Attorney General

By: */s/ Nina D. Bonner*
Nina D. Bonner
Acting Assistant Bureau Chief
Medicaid Fraud Control Unit
New Jersey Division of Criminal Justice
Phone: (609) 292-3262
Fax: (609) 984-2799
Email: BonnerN@njdcj.org

THE STATE OF NEW YORK
By its attorney,
ERIC T. SCHNEIDERMAN
Attorney General

By: */s/ Christopher Y. Miller*
Christopher Y. Miller
Diana Elkind
Special Assistant Attorneys General
New York State Office of the Attorney General
Medicaid Fraud Control Unit
120 Broadway, 12th Floor
New York, New York 10271
Phone: (212) 417-5390/4171
Fax: (212) 417-4604
Christopher.Miller@ag.ny.gov
Diana.Elkind@ag.ny.gov

THE STATE OF OKLAHOMA
By its attorney, SCOTT PRUITT
Attorney General

By: */s/ Christopher P. Robinson*
Niki S. Batt
Christopher P. Robinson
Assistant Attorneys
General Medicaid Fraud Control Unit
Oklahoma Office of Attorney General
313 NE 21st Street
Oklahoma City, OK 73105
(405) 522-2968
Fax: (405) 522-4875
Christopher.Robinson@oag.ok.gov

THE STATE OF WISCONSIN
By its attorney,
BRAD D. SCHIMEL
Attorney General

By: */s/ Katie M. Wilson*
Katie M. Wilson
Wisconsin Department of Justice
Assistant Attorney General
Division of Legal Services
17 West Main Street
PO Box 7857
Madison, WI 563707-7857
Phone: (608) 261-8116
Fax: 608-261-7991
wilsonkm@doj.state.wi.us

THE STATE OF WASHINGTON
By its attorney,
ROBERT W. FERGUSON
Attorney General of the State of Washington

By: */s/ Carrie L. Bashaw*
CARRIE L. BASHAW, WSBA # 20253
Senior Counsel
Medicaid Fraud Control Unit
P.O. Box 40114
Olympia, WA 98504
Telephone: (360) 586-8888
Facsimile: (360) 586-8877

SUSMAN GODFREY LLP

By: /s/ *Steven M. Shepard*
William Christopher Carmody (WC-8478)
Arun Subramanian (AS-2096)
Steven Shepard, *Pro Hac Vice*
Elisha Barron (EB-6850)
560 Lexington Avenue, 15th Floor
New York, New York 10022
Telephone: (212) 336 8330
Facsimile: (212) 336 8340
asubramanian@susmangodfrey.com
Shawn L. Raymond, *Pro Hac Vice*
1000 Louisiana St., Suite 5100
Houston, TX 77002
Telephone: (713) 653-7834
Facsimile: (713) 654-6666
sraymond@susmangodfrey.com
Matthew R. Berry, *Pro Hac Vice*
Andres Healy, *Pro Hac Vice*
1201 Third Avenue, Suite 3800
Seattle, WA 98101-3000
Telephone: (206) 516-3880
Facsimile: (206) 516-3883
mberry@susmangodfrey.com

VOGEL, SLADE & GOLDSTEIN, LLP
Shelley R. Slade (Admitted *pro hac vice*)

Robert L. Vogel (SDNY Bar No. RV1527)
Janet L. Goldstein (Admitted *pro hac vice*)
1718 Connecticut Avenue, NW, 7th Floor
Washington, D.C. 20009
Telephone: (202) 537-5900

Attorneys for Plaintiffs United States, Intervening States and Relator David M. Kester